2015-1468
(Reexamination No. 95/001,469)

United States Court of Appeals for the Federal Circuit

BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORPORATION,
Appellant,

v.

PUGET BIOVENTURES, LLC, formerly HUDSON SURGICAL DESIGN, INC.,
Appellee.

Appeal from the United States Patent and Trademark Office Patent Trial and Appeal Board

OPENING BRIEF FOR APPELLANT

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CERTIFICATE OF INTEREST

Counsel for the Appellant certifies the following:

1. The full names of every party or amicus represented by me are: Biomet Orthopedics, LLC and Biomet Manufacturing Corporation.

2. The name of the real party in interest represented if the party named in the caption is not the real party in interest: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: Biomet, Inc.; LVB Acquisition Merger Sub, Inc.; LVB Acquisition, Inc.; Goldman Sachs Group, Inc.; KKR & Co. LP; The Blackstone Group LP; TPG Capital. Zimmer Holdings Inc. is in the process of acquiring Biomet, Inc. in a transaction expected to close during this appeal.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are: From Troutman Sanders LLP: Douglas D. Salyers, Paul E. McGowan, Dustin B. Weeks, and Trenton A. Ward.*

*Trenton A. Ward previously represented Biomet Orthopedics, LLC and Biomet Manufacturing Corporation before the U.S.P.T.O., but is no longer associated with Troutman Sanders LLP

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STATEMENT OF RELATED CASES

The following cases involve U.S. Patent No. 7,344,541 and may be directly affected by this Court's decision:

- *Hudson Surgical Design, Inc. v. Biomet Orthopedics, LLC and Biomet Manufacturing Corporation*, Case No. 3:10-CV-004645-PPS-CAN, District Court for the Northern District of Indiana
- *Hudson Surgical Design, Inc. v. DePuy Orthopedics, Inc.*, Case No. 3:10-CV-00463-HD-CAN, District Court for the Northern District of Indiana
- *Inter Partes* Reexamination of U.S. Patent No. 7,967,822 (Control Number 95/002,152), United States Patent and Trademark Office (on appeal)

There have been no other appeals in or from this same proceeding in the Patent and Trademark Office before this or any other appellate court.

STATEMENT OF JURISDICTION

This Court has exclusive jurisdiction over this appeal under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(b). Appellant Biomet Orthopedics, LLC and Biomet Manufacturing Corporation ("Biomet") appeals from a Decision on Appeal ("Board Decision") and Decision on Request for Rehearing ("Rehearing Decision") by the Patent Trial and Appeal Board ("Board") related to the *inter partes* reexamination of U.S. Patent No. 7,344,541 ("the '541 Patent") (A1057-1123), owned by Appellee, Puget Bioventures, LLC f/k/a Hudson Surgical Design, Inc. ("Hudson").

On February 3, 2015, Biomet timely filed a Notice of Appeal to this Court and served it on the Director of the PTO, pursuant to 35 U.S.C. § 142, 37 C.F.R. § 90.3, and Federal Circuit Rule 15(a)(1).

STATEMENT OF THE ISSUES

1. Whether the Board erred in its claim construction for the Allowed Claims by holding they require a complete resection from one side of the knee.

2. Whether the Board erred in determining that the Allowed Claims are valid over the prior art which discloses complete and partial resections from one or both sides of the knee.

PRELIMINARY STATEMENT

This appeal stems from an *inter partes* reexamination, filed by Biomet in 2010, which presented multiple prior art references invalidating the '541 Patent. The Examiner found that the claimed side cutting knee resection method was well known and all 54 claims were rejected. On appeal, the Board: (1) sustained the Examiner's rejections as to 38 claims (the "Rejected Claims")[1], and (2) reversed the Examiner's rejections as to 16 claims, Claims 31, 33, 35-40, 45, 47, and 49-54 (the "Allowed Claims").

[1] Hudson is not appealing the Rejected Claims.

Biomet submits that the Board's decision on the Allowed Claims was based on faulty claim constructions and a misreading of the prior art. The Board failed to recognize that the Allowed Claims, just like the Rejected Claims, contained open-ended claim language—such as "at least one" and "at least a portion of"—which meant that the claimed cut guide need not be located on only one side of the knee and that the claimed cut need not result in a complete resection. While the Board properly found that the open-ended language in the Rejected Claims meant that the prior art methods performing resections from one or both sides of the knee invalidated those claims, the Board overlooked the identical open-ended language of the Allowed Claims.

The Board also improperly characterized the claimed method in all of the Allowed Claims as "the resection is completed by using a single cut guide to cut from one side to the other." A26 . The Board's "complete resection from one side" construction for the Allowed Claims was not proposed by Hudson and does not match the claim language, but, even if it did, the prior art taught a complete resection by cutting from one side to the other.

Under either a proper claim construction or under the Board's improper construction the prior art of record anticipates and/or obviates the Allowed Claims. The Samuelson, Biomet, and Protek references each disclose a dual-armed cutting guide, with each arm being movable to wrap around one side of the knee so that

the knee can be cut from either side. These references not only expressly disclose a cutting guide on one side used to cut into the other side but also disclose an entire resection of the knee from only one side —and thus are anticipatory, even under the Board's improper construction.

STATEMENT OF THE CASE AND FACTUAL BACKGROUND

A. The '541 Patent and Claims at Issue

The '541 Patent issued with 54 claims. A1057-1123. The specification is almost exclusively devoted to using a milling bit for resection, describing the use of saw blades as a "sub-optimal cutting tool." A1100. Although the claims are long, with numerous claim limitations, the relevant concepts for this appeal involve the placement of a cut guide on the side of the knee that is used to guide a saw blade during a knee resection. While both the Rejected Claims and the Allowed Claims use slightly different language, they all include two common features: (1) a "positioning" step that locates a cut guide (or slot in the cut guide) relative to a medial or a lateral side of the knee; and (2) a "cutting" step that describes how the cut guide (or slot in the cut guide) is used to create a resected surface on the knee. *See* Allowed Claims 31, 33, 35-40, 45, 47, and 49-54. (A2814, A2829-51).

The Allowed Claims are addressed in two groups: (1) Claims 35-38 and 49-52 ("Unamended Claims") and (2) Claims 31, 33, 39-40, 45, 47, and 53-54 ("Amended Claims"). The Unamended Claims were originally dependent claims

that were rewritten in independent form during the reexamination. The Amended Claims were also originally dependent claims, but the independent claims from which they depend were amended during the reexamination.[2]

B. Reexamination Proceeding

After being sued for patent infringement by Hudson,[3] Biomet filed its Request for *Inter Partes* Reexamination ("Request") on October 15, 2010. A156-213. Biomet proposed rejections of all claims based on seven prior art references (A169, A183-213), including the three at issue in this appeal: U.S. Patent No. 5,611,802 to Samuelson, *et al.* ("Samuelson") (A2171-88); Freeman-Samuelson Total Knee System, Published by Biomet ("Biomet") (A2189-2247); and Protek F/S Modular Total Knee Replacement System, Published by Protek ("Protek") (A2279-2336).

The Examiner granted the Request on November 10, 2010 (A29-43) and issued a Non-Final Office Action on November 23, 2010 (A44-56). The Examiner recognized the open-ended nature of the claim language that read on numerous side cutting knee resection approaches in the prior art references, and adopted

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[2] The '541 Patent will expire on December 24, 2015, before a certificate of reexamination is likely to be issued. Thus, as a practical matter the Amended Claims may never issue. 35 U.S.C. § 251.

[3] The underlying litigation has been stayed pending the outcome of the *inter partes* reexamination.

virtually all of Biomet's proposed rejections, including those based on Samuelson, Biomet, and Protek. A49-52.

On April 22, 2011, Hudson filed its response, which included a first set of claim amendments for every independent claim. A2809-55. By these amendments, Hudson sought to avoid the prior art by removing some open-ended terms related to the positioning of the cut guides (e.g., "positioning the femoral cut guide to extent toward and generally along [at least] only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee") (A2816, amended Claim 13, deleted terms in brackets and additions underlined). As noted in Biomet's May 23, 2011 Written Comments (A2856-65), however, even after the amendments, numerous open-ended terms (e.g., "at least one" and "at least a portion") remained in the claims, and thus the claims remained non-limiting.

The Examiner issued an Action Closing Prosecution on August 29, 2011 (A57-99), and a Right of Appeal Notice on May 21, 2012, (A100-151), which maintained the rejections of all Claims. Hudson and Biomet both appealed to the Board.

On April 30, 2014, the Board Decision affirmed the Examiner's rejections as to 46 claims of the '541 Patent, namely, Claims 1-34, 39-49, 53 and 54. (A10-13). The Board first determined as a matter of claim construction that the open-ended

claim language "allows for the presence of additional cutting guide surfaces" and agreed with the Examiner "the claims can be defined by only a portion of one of the guides of Samuelson." A7-9. The Board then sustained the Examiner's rejections because "the claims as written allow for other guide surfaces that may be placed anywhere on the bone" and that Hudson's arguments to overcome the prior art were "not commensurate with the scope of the claims as construed by the Examiner." A10-11.

The Board determined that the Unamended Claims 35-38 and 49-52, however, were patentable and reversed the Examiner's anticipation rejections based on Samuelson, Biomet, and Protek (A9-11, A13, A18) and obviousness rejections based on the combination of Samuelson and Protek (A14).

In making this decision as to Unamended Claims, the Board accepted Hudson's argument that "Samuelson does not disclose using a medial- or lateral-placed guide to cut from that side to the other side using only the single guide." A9. The Board relied on Claim 35's language "wherein positioning the tibial cut guide locates the tibial cut guide generally medially and . . . further includes cutting a lateral side of the tibia" to support reversing the Examiner.

Hudson and Biomet both requested rehearing of the Board Decision. A3492-96, A3497-3510.

Biomet's rehearing request pointed out that the Board had improperly construed the Unamended Claims as requiring cutting one side of the knee from a cut guide positioned only on the other side of the knee. A3498-3504. Biomet also pointed out that even under the Board's improper construction, Samuelson, Biomet and Protek all taught complete and partial resections from one side only. A3504-3509.

Hudson's rehearing request argued that a subset of the claims the Board had rejected, the Amended Claims 31, 33, 39-40, 45, 47, and 53-54, like the Unamended Claims allowed by the Board, "requires a cutting guide to be positioned on one of the medial or lateral sides of the bone and used to cut across the bone to the opposite or contralateral side." A3495.

In its opposition to Hudson's rehearing request, Biomet pointed out that the Amended Claims all contained open-ended language that made them invalid for the same reason as the Rejected Claims. A3513-19. Biomet further pointed out that cutting a lateral side using a medial side cutting guide was necessarily done by any side cutting approach as a surgeon could not stop a resection exactly at a midpoint line between those sides. A3522-23.

On December 2, 2014, the Rehearing Decision determined that the Unamended and Amended Claims were patentable. A20-27.

When rejecting Biomet's rehearing request for the Unamended Claims, the Board stated while "by way of the affirmed rejections, that the claims do not preclude additional guides or guide surfaces. *See* Dec. 7. It is only the language of the claims subject to the reversed rejections that specifically requires using a single cut guide to cut into the other side." A23 (citing A8). The Board did not address, however, Biomet's second argument that even under the Board's construction, Samuelson, Biomet and Protek all taught complete and partial resections from one side only.

When accepting Hudson's rehearing request for the Amended Claims, the Board made several claim construction findings indicating its belief that all of the Allowed Claims had the same construction. For instance, "[e]ach of the dependent claims at issue recites language that conveys that the cut guide is used on one side of the bone to cut the other side." A24. In order to overcome Biomet's argument that any side cutting approach would necessarily entail cutting into the opposite side of the knee, the Board, for the first time, found that "the Patent Owner's claims describe a complete resection, whereas the Requester's proposition that cutting into the other side falls within the scope of the claims only describes a partial resection that must then be completed using a different cutting guide, which is not the same as what is claimed." A26. This "complete resection" construction

had not been proposed by Hudson, and as shown below, is not supported by the method described in any of the Allowed Claims.

C. Overview of the Prior Art

1. Samuelson

Samuelson is directed to a "method and apparatus for resecting a long bone," specifically, for resecting the "distal end of the femur and the proximal end of the tibia" to prepare the knee "to receive a prosthetic knee joint." A2181. Samuelson contains multiple disclosures in which "a pair of saw guide arms are pivotably and permanently attached to the saw guide body and partially wrap around the bone." A2417.

As shown in Figure 11, to perform a resection of the tibia, block 332 is placed on the anterior side of the tibia, and one of the swing arms of the tibia resection guide assembly, which is defined by "arms 334 and 360[, is] swung into position as a unit against the proximal end of the tibia 28 such that the plate 336 rests substantially flush against the side of the bone." A2187. As a result, the space/slot 370 is positioned along one of the medial or lateral sides of the knee. Samuelson teaches that:

> the surgeon positions a bone saw blade in the space 370 formed between the swing arms 334 and 360 and resects the proximal end of the tibia 28. Reciprocal movement of the saw blade through the space 370 resects the bone. The assembly 278 is thereafter removed.

A2187. This portion of Samuelson teaches a one arm resection technique in which a complete resection of the proximal end of the tibia is performed using a cut guide positioned along a portion of the anterior side of the knee and one of the medial or lateral sides of the knee. Samuelson also enables a two arm resection technique in which both arms are used in the resection.

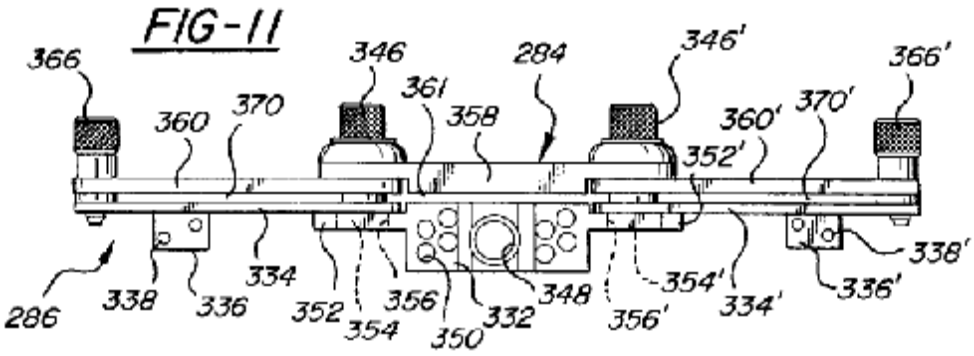
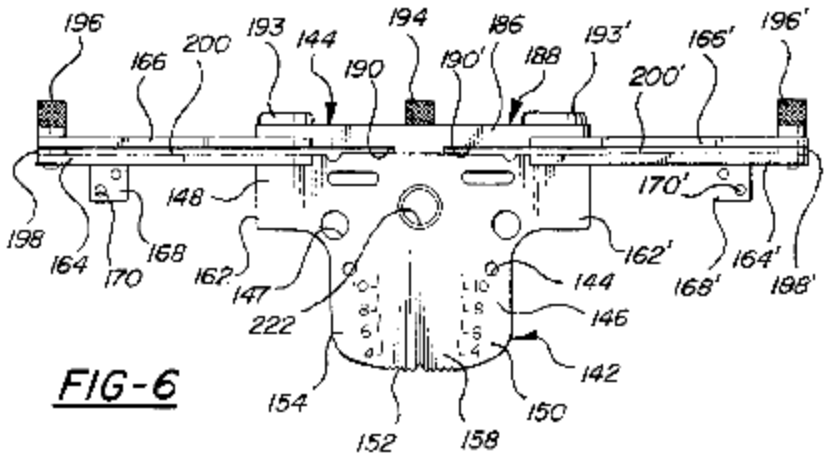


Fig. 6 of Samuelson shows a similar dual armed distal resection guide assembly for resection of the distal end of the femur that can be similarly used for a one arm or two arm resection approach. A2184.



Claim 10 of Samuelson describes a method of resecting the bone by moving a single "laterally extending member" from a first position "spaced apart from the bone" to a second position "adjacent to the bone" and inserting a blade in a "constrained opening" in that laterally extending member and "resecting the bone by movement of the blade of the saw." A2187.

Thus, Samuelson contains multiple descriptions of performing a resection of the end of the knee using a cut guide positioned along only one or both of the medial or lateral sides of the knee.

2. Biomet

Biomet describes "the surgical technique of M.A.R. Freeman, M.D., F.R.C.S., and Kent M. Samuelson, M.D.," who is also an inventor of the Samuelson patent. A2191. The technique disclosed in Biomet is very similar to that of Samuelson and includes the steps of a "Distal Femoral Resection" (A2205) and a "Proximal Tibial Resection" (A2207).

For example, Figure 19 shows a "tibia resection guide" to perform the "Proximal Tibial Resection." A2207-08. The "tibia resection guide[] is centered on the front of the tibia" and one arm of the guide, which together with an "optional saw capture plate[]" forms a slot in the guide, is pinned to the medial side of the tibia. A2207-08. However, "[b]ecause of the position of the patellar tendon it is not possible to use the cutting guide arm on the lateral side." A2208.

At this point, "the proximal tibia is cut along the cut block." A2208. Thus, Biomet expressly teaches the use of a cut guide positioned along a portion of the anterior side and using only one of the medial or lateral sides to resect the entire end of the tibia.

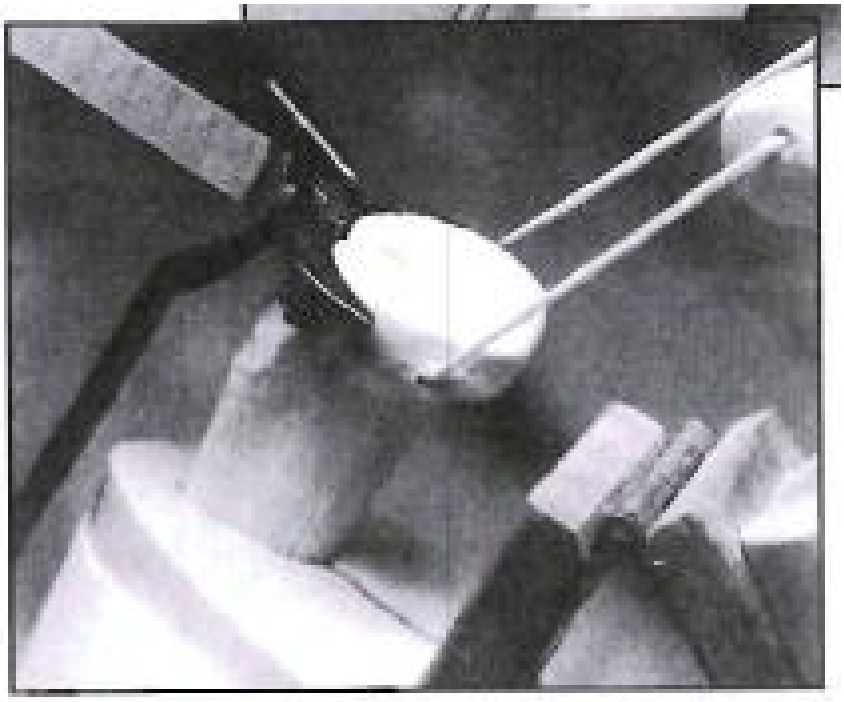


Figure 19

Similarly, Figures 6 and 9 show a "Distal Femoral Resection" is performed using a "distal femoral resection guide." The guide includes a "spring loaded valgus arm" that, "together with a capture plate" form a slot along the arm and a portion of the block that is positioned on the anterior side of the femur. A2204-05. In Figure 9, the arm is positioned along one of the medial or lateral sides of the femur, and "[t]he distal femur is cut flush with the block and its arms." A2205.

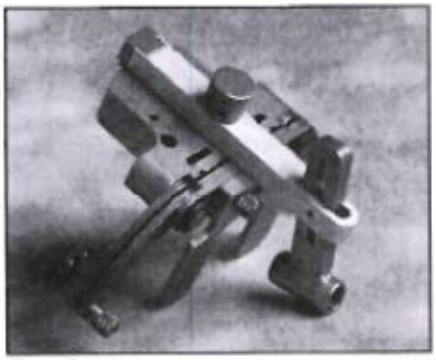


Figure 6

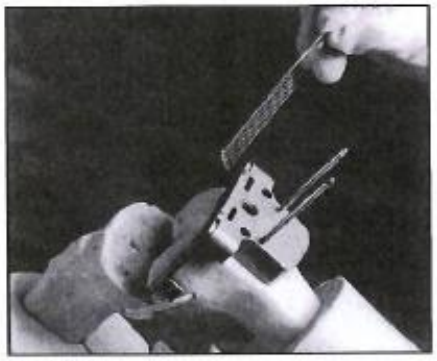


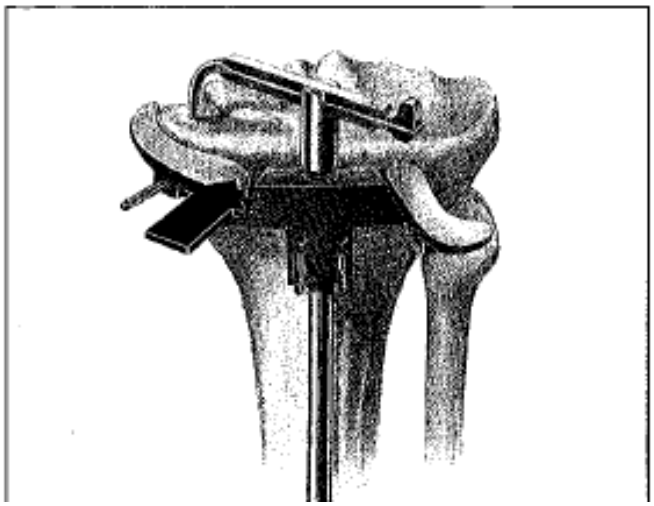
Figure 9

3. Protek

Protek discloses another version of "Freeman Samuelson Arthroplasty." A2286. Like Samuelson and Biomet, the method includes "Resection of the Proximal Tibia" (A2297) and "Distal Femoral Resection" (A2301).

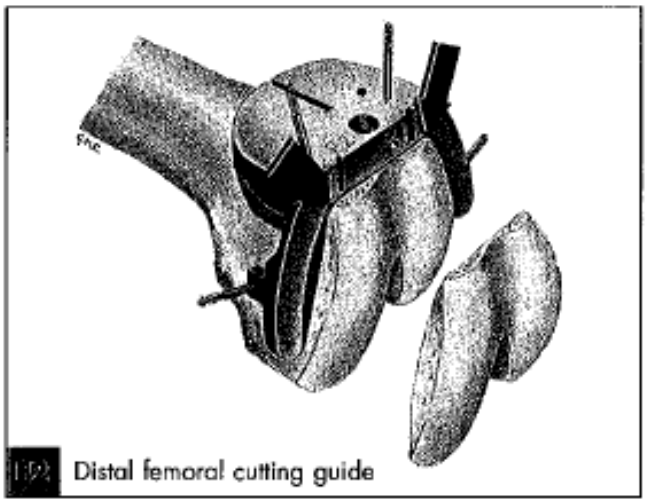
The figure below shows the tibial resection is performed using a "Tibia cutting guide" "centered on the front of the tibia," which includes moveable "arms that wrap around the tibia medially." A2297. Although the guide includes two arms, Protek teaches that only the medial arm of the tibia cutting guide is placed around the tibia and used for resection: "[b]ecause of the position of the patellar tendon[,] it is not possible to use the cutting guide arm on the lateral side." A2297. Once the guide is positioned along a portion of the anterior side and the medial side, "the proximal tibia is cut along the top surface of the guide." A2297.

Step 2: Resection of the Proximal Tibia.



To perform the "Distal Femoral Resection," a "Distal femoral cutting guide" "is placed on the flat anterior surface" of the femur with the moveable arms extending on both the medial and lateral side of the distal femur. A2301. As shown in the figure below, the guide enables resection of the distal femur using a saw blade from either the medial or lateral side of the knee. A2301.

Step 5: Distal Femoral Resection.



Protek expressly recognizes that its cutting guides can be slotted or unslotted. A2291. Additionally, Protek discloses the use of a "Tuke Bone Saw" having a "blade [that] will cut on all its edges" such that it "functions as both an end-cutting and a side-cutting reciprocating saw blade and so can be advanced through the bone from any angle." A2291.

SUMMARY OF THE ARGUMENT

The Allowed Claims are directed to a method of knee resection that includes a step of "positioning" a cut guide adjacent one side of the knee and a step of "cutting" the knee using that cut guide. The Board made three fundamental errors in its claim construction of both the "positioning" step and the "cutting" step. First, while using slightly different phraseology, all of the Allowed Claims contain open-ended language that does not restrict the position of the cut guide to only one side of the knee. Second, none of the Allowed Claims require that the cutting is done only from one side of the knee. Third, none of the Allowed Claims require that the claimed cutting step results in an entire resection. These errors in construction as to both the required *position* of the cut guide and as to how much of the bone must be *cut* and from where led the Board to ignore invalidating prior art that matched the open-ended nature of these claims when properly construed. Even under the Board's erroneous "entire resection from only one side" construction, the Board failed to recognize that multiple prior art references taught

an entire resection using a guide positioned on only one side of the knee.

ARGUMENT

I. STANDARD OF REVIEW

The Federal Circuit reviews legal conclusions of the Board *de novo*. *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013). Factual findings of the Board are reviewed for substantial evidence. *Id*. Anticipation is a question of fact that the Court reviews for substantial evidence. *Id.* Obviousness is a question of law reviewed *de novo* based on underlying facts reviewed for substantial evidence. *Id*.

The Board's decision rests partially on the resolution of claim interpretation issues, which this Court reviews *de novo*. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012). If this Court disagrees with the Board's claim construction, questions of anticipation and obviousness will be determined under this Court's claim construction. *Flo Healthcare Solutions, LLC v. Kappos*, 697 F.3d 1367, 1375 (Fed. Cir. 2012).

II. THE BOARD ERRED IN ITS CLAIM CONSTRUCTION THAT "THE ENTIRE RESECTION IS BEING DONE USING A GUIDE ON ONE SIDE TO COMPLETE THE RESECTION"[4]

A. The Unamended Claims Are Not Limited to Cutting One Side of the Knee Using a Cut Guide Positioned Only on the Other Side of the Knee, Nor Do They Require a Complete Resection

The Board misconstrued the Unamended Claims when it found that they require "a single guide placed on one side or the other and used to cut into the other side (i.e., from the lateral into the medial side or vice versa), for example as in claim 35." A9 (emphasis added). To the contrary, these claims broadly claim a method that "includes" the steps of: (1) *positioning* a cut guide "generally" on one side of the knee, but not "only" on one side, and (2) *cutting* one side of the knee by guiding a cutting tool from "at least one" side, which does not prohibit and thus could "include" guiding the cutting tool from both sides of the knee. Specifically, by including multiple open-ended terms such as "at least a portion" and "at least one," the Unamended Claims do not dictate that one side of the knee is cut "only" from the other side.

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[4] Biomet's claim construction arguments rely on the ordinary meaning of the claim language. The '541 Patent's specification provides no meaningful guidance on the interpretation of the claims since it is focused on using a milling bit for resection, instead of the claimed "cutting tool with a saw blade," and even describes the use of saw blades as a "sub-optimal cutting tool." (A1100). Thus, neither the Board nor either party relied on any discussion of the specification during reexamination. *See also* A2857-60.

The Board further misconstrued the Unamended Claims when, to overcome Samuelson (A2171-88), it characterized the claims as requiring a "complete resection" not a "partial resection." A26. Yet, the claim language only requires creating "at least one resected surface," and thus it is not tied to a complete resection.

The limitations at issue in this appeal deal with the steps of "positioning the . . . cut guide" and "guiding a cutting tool . . . by using the . . . cut guide to create at least one resected surface." Exemplary Claim 35[5] contains two limitations for the "positioning" step and two limitations for the "guiding" (i.e., "cutting") step. As explained below, each limitation uses open-ended language that (1) does not limit the position of a cut guide to only one side of the knee, and (2) does not require cutting one side of the knee from the other side of the knee, much less performing a "complete resection." Exemplary Claim 35 (relevant portions presented for this appeal) provides:

> **Claim 35.** (Amended) A method for a knee implant procedure comprising:
>
> . . .
>
> positioning the tibial cut guide generally adjacent at least a portion of an anterior side of the tibia and at least one of the medial side or the lateral side of the knee; and

[5] Claims 36-38 and 49-52 contain substantially identical limitations to Claim 35 as they simply switch "generally laterally" for "generally medially" and "femoral cut guide" for "tibia cut guide."

> guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade by using the tibial cut guide to create at least one resected surface on the proximal end of the tibia by guiding the long axis of the saw blade from at least one of the medial side or the lateral side of the knee; and
>
> . . .
>
> wherein positioning the tibial cut guide locates the tibial cut guide generally medially and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a lateral side of the tibia.

A2830-32.

1. The First Positioning Limitation does not preclude a tibial cut guide positioned on both the medial AND lateral sides

The first positioning limitation in Claim 35 recites "positioning the tibial cut guide generally adjacent **at least a portion of an anterior side** and **at least one of the medial side or the lateral side** of the knee." A2831-32. The Board overlooked the open-ended phrases of "at least a portion" and "at least one of," and instead read this claim to require the cut guide to be "on [only] one side." A26, A9. During reexamination Hudson attempted to overcome the prior art by amending the language of original Claim 13 from "**at least one of** the medial side or the lateral side of the knee" (A1118) to "**only one of** the medial side or the lateral side of the knee" (A2817), but Hudson did not incorporate that **"only one"** amendment when it rewrote dependent Claim 35, which depends from Claim 13,

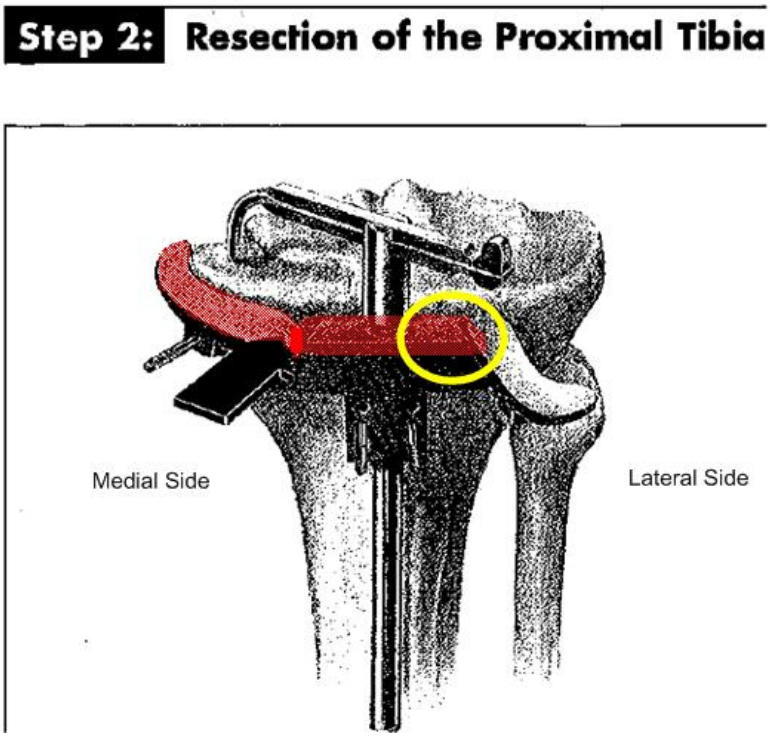
into independent form. Rather, the original broad language of **"at least one"** side remains in Claim 35, and its open-ended nature cannot be ignored.

Thus, this limitation does not require the cut guide to be on "**only one**" side and allows the cut guide to be positioned on *both* the medial and lateral sides. As written, the first positioning limitation would be satisfied by three cut guide positions: (1) generally adjacent at least a portion of the anterior side and the medial side; (2) generally adjacent at least a portion of the anterior side and the lateral side; or (3) generally adjacent at least a portion of the anterior side, and both the medial side and the lateral side. Each possibility satisfies the "at least one" claim language and the Board wrongly limited the claim to "a single guide placed on one side." A9.

2. The Second Positioning Limitation does not preclude the tibial cut guide from being located partially laterally

The second positioning limitation in Claim 35 recites that the step of "positioning the tibial cut guide locates the tibial cut guide generally medially." A2832. Importantly, while the second limitation requires the cut guide to be located generally medially, it does not preclude the cut guide from also being located at least partially laterally. A cut guide can be located generally medially and still have portions of the cut guide located at least partially on the lateral side. For example, the annotated figure below from the Protek reference (A2297) shows a cut guide (highlighted in red) having a cutting surface generally positioned along

the medial side even though some of it (the circled portion) is also on the lateral side. This orientation necessarily satisfies the claim limitation because the cut guide is positioned "generally medially," but at the same time is positioned with a portion of the cut guide on the lateral side as also allowed by the claim.



The Board fundamentally misconstrued Claim 35 when it said the claim required "a single guide placed on one side" (A9 (emphasis added)) since the "generally medially" limitation allows the guide to be on both the medial and the lateral sides.

3. The First Guiding Limitation does not preclude additional resected surfaces nor preclude resection from either the medial OR lateral sides

The first guiding limitation of Claims 35-38 and 49-52 contains two open ended terms: "guiding a cutting tool . . . by using the tibial cut guide to create **at least one resected surface** . . . by guiding the . . . saw blade **from at least one of the medial side or the lateral side** of the knee." A2832.

The first open ended guiding term, "at least one resected surface," indicates that the cutting tool creates at least one resected surface, but "at least one" does not preclude other resected surfaces. Nor does this term define the claimed "one resected surface" to be a complete resection of the entire proximal end of the knee. Instead, it is just "one resected surface" and, thus, "other resected surfaces" that could be created in other ways, are allowed.

The second open-ended guiding term, "from at least one of the medial side or lateral side," like the first positioning limitation, does not require guiding the saw blade from "**only one**" side and allows the claimed guiding to be done from *both* the medial and lateral sides. During reexamination, Hudson attempted to overcome the prior art by also amending the guiding the saw blade language of original Claim 13, "**from at least one of** the medial side or the lateral side of the

knee," to the narrower "**the** medial side or the lateral side of the knee."[6] A2815-17. But, Hudson did not incorporate this narrowing **"the"** amendment when it rewrote dependent Claim 35, which depends from Claim 13, into independent form. Just like the first positioning step, the original broad language of **"at least one"** side remains in the first guiding step of Claim 35, and its open-ended nature cannot be ignored.

As a result, guiding the saw blade can be from any one of three positions: (1) the medial side, (2) the lateral side, or (3) both the medial side and the lateral side.[7] Therefore, this language is satisfied as long as "at least one resected surface" of the bone is created from "at least" one or both of the medial and lateral sides of the knee, but the open-ended nature of the claim does not require guiding the saw blade from **only** the medial or lateral side of the knee.

Importantly, while both the positioning steps (Section II.A.1. above) and guiding steps (Section II.A.3. above) of Claims 35-38 and 49-52 use the identical orientation term of "at least one of the medial side or the lateral side of the knee,"

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[6] The antecedent basis for this "the" is the positioning step amendment of original Claim 13, discussed above, which would have positioned the tibia cut guide on "only one of the medial side or lateral side of the knee." A2831-32. Despite this narrowing amendment, Amended Claim 13 was found invalid over Samuelson. A11-12.

[7] The "at least" claim language also does not preclude guiding the saw blade from other positions, including the anterior side – particularly since the claim requires at least a portion of the cut guide to be positioned on "at least a portion of the anterior side of the knee." A2831-32.

only the positioning step contains the further limitation that the cut guide is located "generally medially." A2832. The guiding step was not similarly limited in its orientation. While other claims in the reexamination unsuccessfully tried to limit the cutting direction as coming from only one of the medial side or the lateral side, like Amended Claim 13 discussed above, Claim 35 does not. A2830-32. Accordingly, while the cut guide is to be positioned "generally medially," guiding the saw blade from the lateral side is still a claimed guiding orientation. The Board thus erred when it construed this claim as requiring "a single guide placed on one side or the other and used to cut into the other side." A9.

4. The Second Guiding Limitation does not preclude resection occurring from the lateral side nor require a complete resection

The second guiding limitation of Claims 35-38 and 49-52 recites that guiding the saw blade with the cut guide "**further includes cutting a lateral side** of the tibia." A2832. Unlike the first guiding limitation, however, this claim language does not dictate from which direction the lateral side is to be cut – only that a lateral side is, indeed, cut. Moreover, because the second guiding limitation begins with "further includes," it is distinct from and not tied to the resection approach claimed in the first guiding limitation that included a directional limitation (i.e., that the saw blade is guided "from at least one of the medial side or the lateral side"). This construction is confirmed by the fact that the "further

includes" limitation relates only to the first part of the "guiding the cutting tool" step, and thus is not tied to the second part of that step "to create at least one resected surface" by guiding the saw blade "from at least one of the medial side or the lateral side of the knee."[8] This "further includes" limitation simply says that the guiding limitation also included cutting some unspecified portion of a lateral side of the tibia, but not the resected surface, in some unspecified way, but not from the medial or lateral side.

Therefore, the broadest reasonable interpretation of Claim 35's two guiding/cutting steps requires that (1) at least one resected surface is made by guiding the saw blade "from at least one of the medial side or the lateral side of the knee" and (2) the guiding step further includes cutting a lateral side of the tibia. Since, as shown above, the two positioning limitations allow for the cut guide to be

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[8] A close reading of the claim language confirms this construction: the "further includes" limitation does not modify the last section of the guiding limitation by saying, for example, that "guiding the long axis of the saw blade from at least one of the medial side or lateral side of the knee *further includes cutting a lateral side*." Nor does the claim language say "creating at least one resected surface on the proximal end of the tibia *further includes cutting a lateral side of the tibia*." Instead, the claim language only modifies the first part of the guiding limitation, i.e., "guiding the cutting tool having a saw blade with the cutting edge at the distal end of the long axis of the saw blade *further includes cutting a lateral side of the tibia*." A2832. The claim drafter had the opportunity to, but did not, restrict the "further includes" limitation to either the earlier claimed direction of cutting or the earlier claimed resected surface limitations. This distinction is necessary to properly construe the claim's scope, but it was ignored by the Board's claim interpretation.

positioned partially on the lateral side, the lateral side can be cut from the cut guide in that position. Moreover, since the cut guide must also be on "at least a portion of the anterior side," anterior side cuts are not precluded – including anterior side cuts of the lateral side. There simply is no requirement in Claim 35, however, that the lateral side must be cut from the medial side and only from the medial side.

Finally, adding "cutting a lateral side" (A2832) does not create a complete resection. The claim language does not say how much of the lateral side is cut, nor does it even say that the cutting results in a resected surface. A bone can be cut without creating a resected surface, e.g., a saw blade could cut a slot into the bone without creating a flat surface on which the implant could be placed.

In other words, Claim 35 does not *require* that the guiding/cutting step includes cutting a lateral side of the tibia from the medial side of the tibia. As a result, the Board misconstrued Claim 35 when it found that it required "a single guide placed on one side or the other and used to cut into the other side (i.e., from the lateral into the medial side or vice versa), for example as in claim 35." A9 (emphasis added). And, the Board further erred when it construed this claim as requiring a complete resection. A26.

5. The Unamended Claims are open-ended and do not preclude the performance of additional intervening steps

Claims 35 includes the step of "resecting a proximal end of a tibia of the knee **including at least**" (A2831) performing the positioning step and the

guiding/cutting step just described. Because the claim uses the transitional phrase "including at least," however, "resecting a proximal end of the tibia" can also include positioning and/or guiding/cutting steps other than those expressly recited in the claim. The inclusion of additional steps is also confirmed by the unconnected nature of each claim element, such that, e.g., none of the claimed steps are required to be performed in any particular order or require that limitations of one step be used in the other steps. *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1309 (Fed. Cir. 2014) ("Steps in a method claim need not necessarily be performed in the order they are written" unless "grammar, logic, the specification, or the prosecution history require the steps to be performed sequentially") (emphasis added) (citations omitted).

The Board ignored this additional open-ended aspect when it allowed Claim 35 to issue over the prior art. For example, the Board said that "Samuelson teaches a medial cutting guide to cut the medial side of the bone and a lateral cutting guide to cut the lateral side, but nowhere explicitly discloses a single cutting guide placed on one side or the other and used to cut into the other side" as in Claim 35. A9-10. Even if the Board's interpretation of the prior art is correct, which Biomet disputes (see Section III(D)), the Board improperly construed Claim 35 as requiring the steps to be performed in a certain order and thus improperly precluded the presence of intervening, albeit unclaimed, steps. *Apple Inc.*, 757 F.3d at 1309.

Claim 35 recites that resecting the tibia "includes at least": (1) the recited positioning step in which the cut guide is both adjacent to the anterior side and at least one of the medial or lateral sides and is located "generally medially," and (2) a guiding/cutting step that both creates at least one resected surface by sawing from at least one of the medial or lateral sides and "further includes" cutting the lateral side of the knee. A2831-32. Claim 35, however, doesn't preclude additional steps[9] and doesn't require that either aspect of the recited guiding/cutting step be performed immediately after the recited positioning steps.

For example, the guiding/cutting step does not state that after positioning the tibial cut guide generally medially, the cut guide must be used in that position to cut the lateral side. As a result, the further guiding/cutting step of cutting the lateral side does not have to be performed while the cut guide is positioned "generally medially" and the cut guide can be moved before the step of cutting the lateral side is performed. *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1005 (Fed. Cir. 2014) (citing *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.")). Thus, Claim 35

[9] Claim 35 does not use the language found in other claims that precluded the cut guide from being in other locations. For example, Claim 1 as amended said that the cutting guide surface was positioned "along only one of a medial side or a lateral side" and "with no other portion of the guide surface" positioned on the other side. A2810. Claim 35 is not so limited.

reads on a prior art method of resecting the tibia, which involves: (1) positioning a medial swing arm of the cut guide on the medial side of the knee so that the cut guide is located "generally medially" (claimed positioning step); (2) cutting the medial side of the knee to create one resected surface (first claimed guiding/cutting step); (3) positioning a lateral swing arm of the cut guide on the lateral side of the knee (unclaimed step); and (4) cutting a lateral side of the knee (second claimed guiding/cutting step). This prior art method anticipates the claimed method because it "includes at least" both the claimed positioning step and the two guiding/cutting steps, even though it includes one additional unclaimed step, which is not precluded by the open-ended way in which Claim 35 was drafted.

B. Amended Claims 31, 33, 45, and 47 Are Not Limited to Cutting One Side of the Knee from a Cut Guide Positioned Only on the Other Side of the Knee and Do Not Require a Complete Resection

The Board erred when it construed Amended Claims 31, 33, 45, and 47 as conveying "that the cut guide is used on one side of the bone to cut the other side as part of the resection in the same way that we determined was the case for Claims 35-38 and 40[sic]-52 in our original decision." A24. Just like the Unamended Claims, Amended Claims 31, 33, 45, and 47 use open-ended claim language when describing how to position a cut guide and how to cut an end of the knee.

Independent Claim 9 (amended) and exemplary Claim 31(unamended)[10]

(added language underlined) provide in relevant part:

> **Claim 9.** A method for a knee arthroplasty procedure comprising:
>
> providing a **cutting guide having a slot** . . .
>
> **positioning the cutting guide** in a position proximate an end of one of a femur or a tibia **with at least a portion of the slot facing** the end of the one of the femur or the tibia from **only one of a medial aspect or a lateral aspect with no other portion of the slot positioned along the other of the medial aspect or the lateral aspect**;
>
> extending the saw blade though the slot;
>
> **cutting the end of the one of the femur or the tibia** by moving the cutting tool in a direction along the long axis, the direction of the long axis being at least one of a medial to lateral direction or a lateral to medial direction to create at least a portion of at least one resected surface . . . .
>
> **Claim 31.** The method of claim 9 wherein **cutting the end of the one of the femur or the tibia** by moving the cutting tool in a direction along the long axis **comprises plunging the saw blade through the slot** to create the resected surface on **both** a medial portion or a lateral portion of the one of the femur or the tibia **adjacent to the position of the cutting guide** and a medial portion or a lateral portion of the one of the femur or the tibia **across from and opposite to the position of the cutting guide**.

A2814, A2829 (emphasis added).

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[10] The relevant "positioning" and "cutting" steps in Claims 31, 33, 45, and 47 are substantially identical. *See* A2814, 2829-30 (Claims 31, 33) and A2824-25, A2840-41 (Claims 45, 47).

1. Amended Claims 31, 33, 45, and 47 do not preclude a cut guide with "other" slots positioned at other locations

Claim 9, from which Claim 31 depends, is directed to a method of knee arthroplasty comprising the steps of "providing a cutting guide having **a slot**" and "positioning the cutting guide . . . with at least a portion of **the slot** . . . facing the end of the . . . femur or tibia from only one of a medial aspect or a lateral aspect with no other portion of **the slot** positioned along the other of the medial aspect or lateral aspect." *See* Claim 9 (A2814). Thus, while Claim 9 requires the cutting guide to have "a slot," the *positioning* step only limits the position of "the slot," but it does not limit the position of any portion of the cutting guide itself. Thus, the cutting guide can be located anywhere next to the knee and is not limited by the claim to the location of the slot. The Board previously adopted this interpretation of Claim 9 in affirming the Examiner's rejections of Claim 9. *See, e.g.*, A7-9, A23.

Further, Hudson recognized this same open-ended problem during reexamination and attempted to amend Claim 9 a second time to recite "providing a **single** cutting guide having a **single** slot." A2872. The Examiner, however, refused to enter those amendments for failure to comply with 37 C.F.R. §§ 1.116 & 1.530. *See* A104-110. Accordingly, Hudson cannot now argue the claimed cutting guide is limited to only a single slot.

As shown in annotated Figure 6 of Samuelson below (A2176), the

positioning step of Claim 9 and thus Claim 31 (which contains no further limitation on the position of the cutting guide or "the slot") would read on a reference, such as Samuelson, disclosing a cutting guide with multiple slots because one of the slots on the medial side faces the medial aspect but no portion of *that medial slot* faces the lateral aspect. This is true even if *another slot* on the same cutting guide, which is neither recited in nor precluded by the claims, is on the lateral side and faces the lateral aspect.

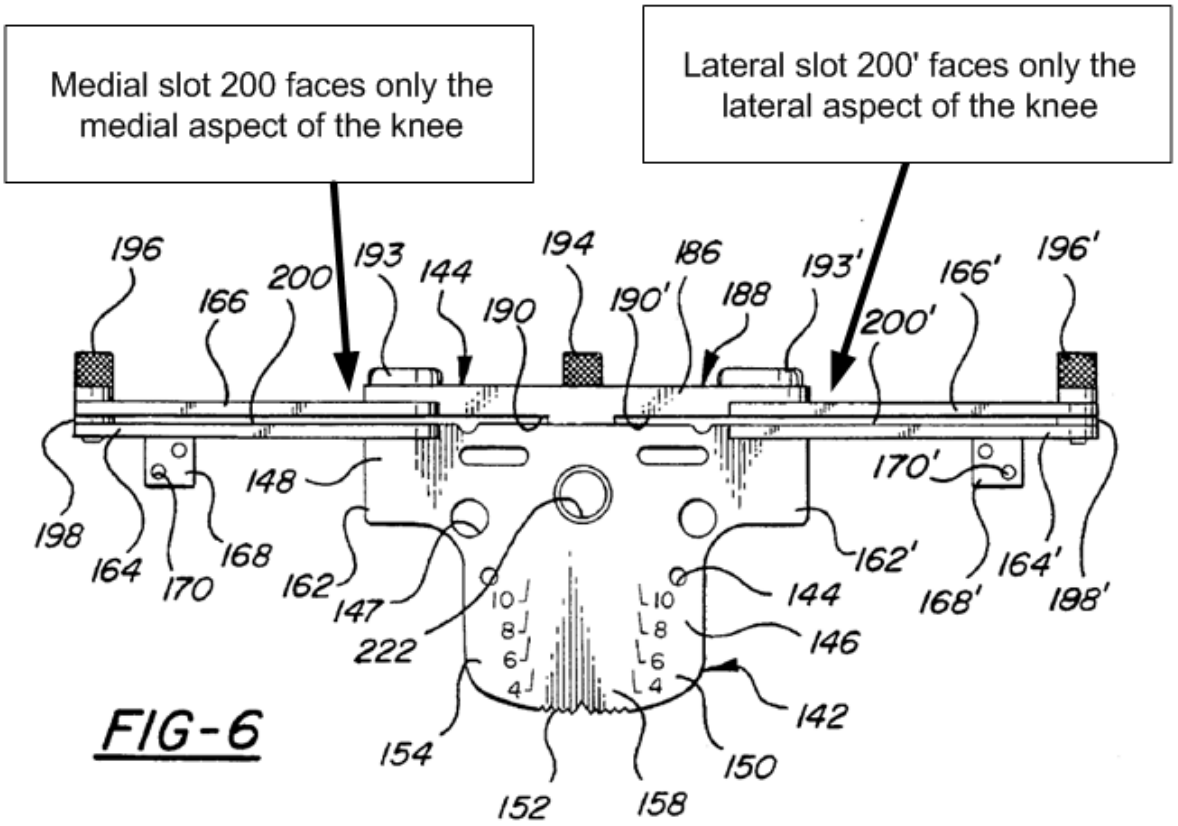


FIG-6

2. Amended Claims 31, 33, 45, and 47 claim using the slot to cut only one side of the knee

The *cutting* step of Claim 31 recites, "wherein cutting the end of the . . .

femur . . . comprises plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion of the . . . femur . . . adjacent to the position of the cutting guide and a medial portion or a lateral portion of the . . . femur . . . across from and opposite to the position of the cutting guide." A2829. Although the position of "the slot" is limited to only one side or the other and "the slot" must be used to create "at least one resected surface" on the bone, in Claim 31 the "portion[s]" of the bone to be cut are specifically defined by their position relative to "the cutting guide." As explained in the preceding section, the claim does not limit the cutting guide location and thus it can be located on any side of the knee, and need not be on the side where the slot is located. So long as the cut includes both (1) "a medial portion or a lateral portion . . . **adjacent to the position of the cutting guide**" and (2) "a medial portion or a lateral portion . . . **across from and opposite to the position of the cutting guide**" (A2829), the claim is satisfied.

As a result of the cutting guide's allowed positions on any side of the knee, Claim 31's requirement that two "portion[s]" be cut does not require that both a medial portion **and** a lateral portion of the knee be cut—so long as two portions are cut.[11] When the cutting guide is located on both the medial and the lateral sides,

[11] The disjunctive term "or" used between the medial portion and lateral portion in each part of this claim confirms that the claim is not saying both a medial portion

Claim 31's *cutting* step can read on cutting only the medial side of the bone. Modified Figure 6A of Samuelson (A2175) below has both swing arms deployed (an allowed configuration for Claim 31), with the cutting guide positioned along both the medial and lateral sides. In this configuration, there are many portions of the medial side of the knee that are "adjacent to the position of the cutting guide" and many portions of the medial side of the knee that are "across from and opposite to the position of the cutting guide." Thus, when only the medial side of the bone is cut using only the medial swing arm slot, cutting occurs on both: (1) a portion of the medial side that is "adjacent to the position of the [medial side of the] cutting guide" ("ADJACENT PORTION" box below), and (2) a portion of the medial side that is "across from and opposite to the position of the [lateral side of the] cutting guide" ("OPPOSITE PORTION" box below).

"and" a lateral portion are necessarily part of the resected surface. It is entirely consistent with the logic of the claim language for a cut on a medial portion to satisfy both parts of Claim 31.

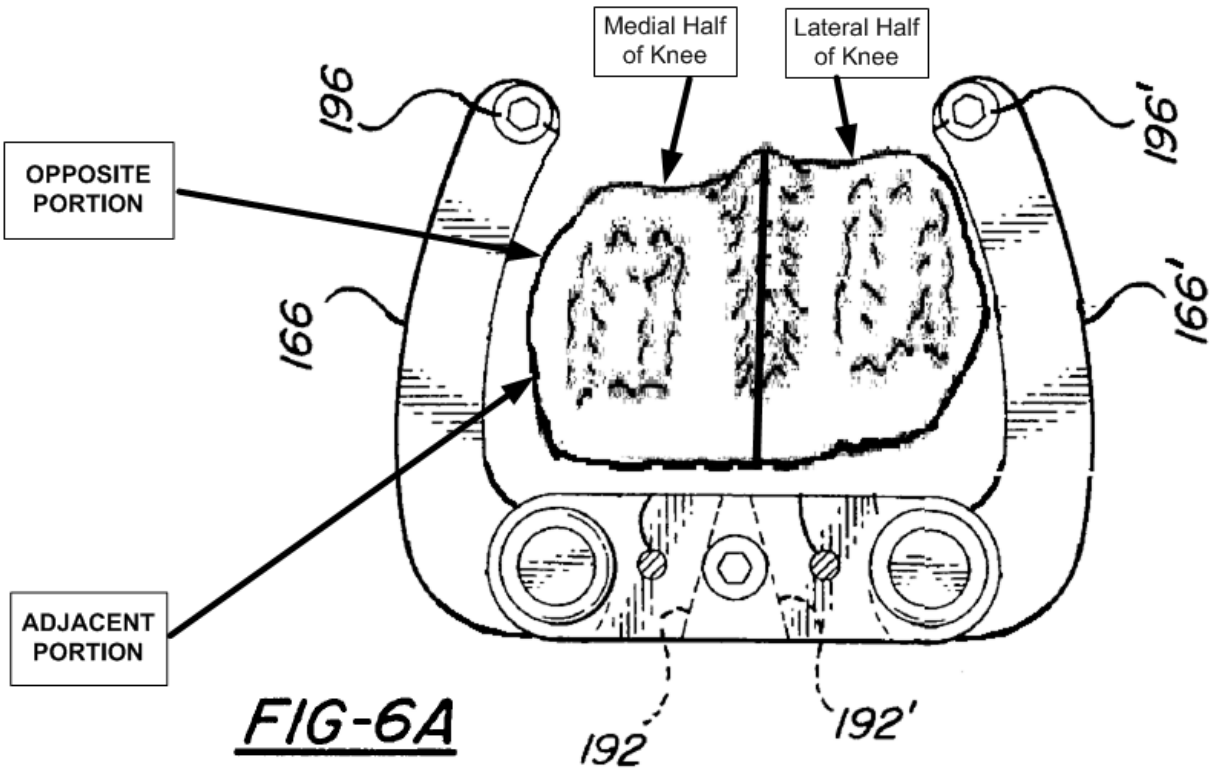


FIG-6A

If Hudson had wanted to simply claim "the cut guide is used on one side of the bone to cut the other side," as the Board has improperly rewritten the claim to mean, the claim could have been drafted in a much less convoluted way. In Claim 31, however, Hudson chose to define the resected surface with reference to the location of the cutting guide, not the location of the slot used for cutting, but placed no limits on where the cutting guide can be positioned. By then using the disjunctive "medial portion *or* lateral portion" to further confuse the claim meaning, Hudson created a claim that contemplates the admittedly strange scenario depicted in annotated Figure 6A (above) where the same medial portion can satisfy both parts of this claim.

3. Amended Claims 31, 33, 45, and 47 do not result in a "complete resection" nor preclude other cutting approaches to create other portions of a resected surface

The Board found that "[Hudson]'s claims describe a complete resection" and that a "partial resection . . . is not the same as what is claimed." A26 . The Board similarly found that completing a resection "using a different cutting guide" is not within the scope of the claims. A26. This "complete resection" construction using one cutting guide for Amended Claims 31, 33, 45 and 47 is flawed for four interrelated reasons.

First, the cutting step of Claim 9 must only "create at least a portion of at least one resected surface." A2814. Creating only a portion of the resected surface equates to a "partial resection" not a "complete resection.

Second, Claim 31 adds a "plunging the saw blade through the slot" limitation to the cutting step but uses the open-ended transitional term "comprising," which means that other cutting approaches and other cutting guides or slots are allowed to create the claimed portion (or other portions) of the resected surface. A2829.

Third, the antecedent basis for "the resected surface" in Claim 31 is the open-ended phrase in Claim 9 "at least a portion of at least one resected surface" as

that is the only prior use of the term "resected surface."[12] A2814, A2829. Thus, the claimed resected surface is a partial resection, and does not require a complete resection.

Finally, Claim 31adds that the "portion of the at least one resected surface" must be on "a medial portion or a lateral portion" of the femur or tibia which confirms that the claim is consistently describing resecting only a portion of the medial or lateral side of the knee bone, not a complete resection.

C. Amended Claims 39, 40, 53, and 54 do not require a Cut Guide Positioned on One Side to cut the Other Side Nor Require a Complete Resection

Like all the Allowed Claims on appeal, the Board erred when it construed Amended Claims 39, 40, 53, and 54 as requiring a complete resection using a cut guide positioned only on one side of the knee. Independent Claim 13 (as amended), dependent Claim 16 (as amended), and exemplary Claim 39[13] (unamended) (added language underlined and deleted portions bracketed) provide in relevant part:

> **Claim 13.** A method for a knee implant procedure comprising:
>
> . . .

[12] This construction is also confirmed by Claim 31 being dependent on Claim 9 and thus it cannot claim a broader scope of resecting than the "portion" set out in the independent claim. A2814, A2829.

[13] All four of these claims contain substantially identical language relating to the relevant cutting guide and cut limitations. A2815-18, A2839.

> **positioning the femoral cut guide** to extend toward and generally **along** [at least] **only a portion of an anterior side of the femur and only one of a medial side or a lateral side** of the knee; and
>
> **guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade** by using the femoral cut guide to create at least one resected surface on the distal end of the femur by **guiding the long axis of the saw blade from** [at least] **the one of the medial side or the lateral side** of the knee;
>
> . . .
>
> **Claim 16.** The method of claim 13 wherein the step of **positioning the femoral cut guide** positions the femoral cut guide **to extend toward and generally along only one of the medial side or the lateral side** of the knee with no portion of the femoral cut guide positioned along the other of **a corresponding compartment of the medial side or the lateral side** of the femur.
>
> **Claim 39.** The method of claim 16 wherein the femoral cut guide extends mediolaterally for a width less than one-half of a width of the femur and **guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade** by using the femoral cut guide further includes **cutting a contralateral compartment relative to the one of the medial side or the lateral side of the femur**.

A2815-17, A2818, A2839 (emphasis added).

1. Amended Claims 39, 40, 53, and 54 do not result in a "complete resection from one side" and allow two separate cuts from two different directions

The Board found that all of "the Patent Owner's claims, describe a complete resection" and that a "partial resection . . . is not the same as what is claimed." A26. The Board similarly found that completing a resection "using a different

cutting guide" is not within the scope of any of the claims." A26. This "complete resection" construction using one cutting guide is flawed for the simple reason that Amended Claims 39, 40, 53 and 54 recite two different cuts from two different directions – neither of which is a complete resection.

Claim 13 describes a first cut using the femoral cut guide "to create at least one resected surface" and that the guiding for this resected surface is done "from the one of the medial side or the lateral side" where the femoral cut guide has been positioned. A2817. This first guiding/cutting limitation dictates what is to be cut (i.e., at least one resected surface) and from which direction (i.e., from the medial or lateral side), but it does not say that a complete resection is done.

With its "further includes" limitation to this guiding/cutting step, Claim 39 adds a second cut in which the femoral cut guide is used to cut "a contralateral compartment." A2839. This second guiding/cutting limitation dictates a second area to be cut (i.e., a contralateral compartment), but it does not dictate from which direction this cut is to be made. While "the femoral cut guide" is also used for the second cut, that guide is specifically claimed to be along the anterior side, so the second cut can be performed from that side. Moreover, the open-ended "further includes" language is modifying only a portion of Claim 13's guiding step – i.e., that portion before the "to create at least one resected surface" portion begins – and thus the additional limitation of Claim 39 is claiming cutting something different

than the claimed "at least one resected surface."[14] In other words, the second cut language is not modifying the "at least one resected surface" language of the first cut (from Claim 13); instead, it simply describes cutting some portion of the contralateral compartment but is not necessarily creating a resected surface. In fact, this second cut language doesn't require a resection at all, just that the contralateral compartment be cut.

As with the Unamended Claims, adding "cutting a contralateral compartment" does not create a complete resection. The claim language does not say how much of the contralateral side is cut, nor does it even say that the cutting results in a resected surface. Cutting a slot in a bone compartment would satisfy the claim but wouldn't necessarily result in a flat surface on which to place the implant.

As with the tortured language used in other claims, Claim 39 cannot be simplified to the Board's "complete resection from one side" construction. The claim contains too many unrelated claim elements to be boiled down to this simple concept and the Board's construction should be rejected.

---

[14] Hudson could have claimed, but did not, that the resected surface of the first cut includes the contralateral compartment of the second cut.

III. THE BOARD ERRED IN DETERMINING THE PRIOR ART DID NOT INVALIDATE THE ALLOWED CLAIMS

A. Samuelson Anticipates All Claims Under Their Proper Construction

Samuelson discloses multiple cutting approaches that allow for the use of one or both of the swings arms in the femoral and tibial cut guides.

For example, Samuelson discloses a One-Sided Cutting Approach with the steps of (1) centering a guide on the anterior side of the knee, (2) positioning a single swing arm to the medial side of the knee, and (3) cutting both sides of the knee from the medial swing arm.

Samuelson also discloses a Two-Sided Cutting Approach with the steps of (1) centering the guide on the anterior side of the knee, (2) positioning the medial swing arm on the medial side, (3) cutting the medial side of the bone from the medial swing arm, (4) positioning the lateral swing arm on the lateral side, and (5) cutting the lateral side of the bone from the lateral swing arm.

Both the One-Sided and Two-Sided Cutting Approaches anticipate all claims under their proper construction.

1. The Unamended Claims

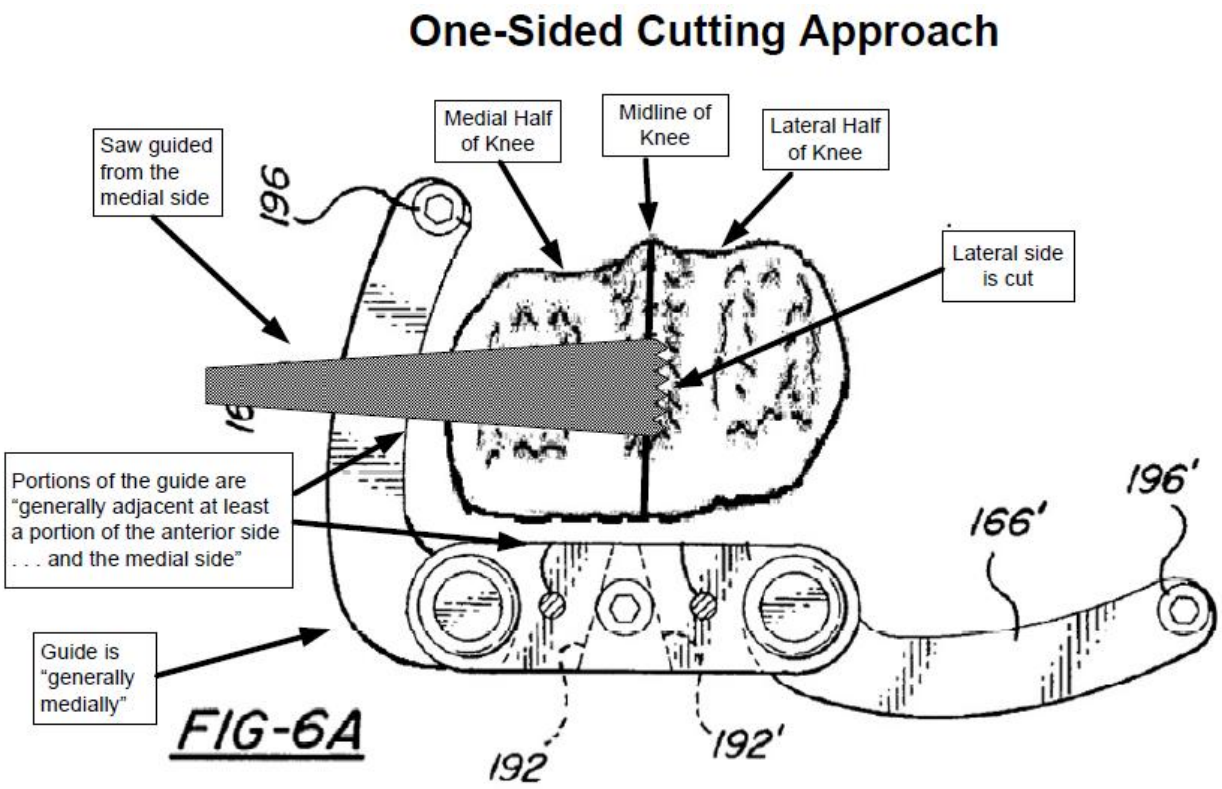
Claim 35 includes the four relevant limitations:

> (1) "positioning the tibial cut guide generally adjacent at least a portion of the anterior side of the tibia and at least one of the medial side or the lateral side of the knee";

> (2) "positioning the tibial cut guide locates the tibial cut guide generally medially";
>
> (3) "guiding a cutting tool . . . using the tibial cut guide to create at least one resected surface on the proximal end of the tibia . . . by guiding the . . . saw blade from at least one of the medial side or lateral side of the knee"; and
>
> (4) "guiding the cutting tool . . . by using the tibial cut guide further includes cutting a lateral side of the tibia."

a. One-Sided Cutting Approach

In the Samuelson One-Sided Cutting Approach, as depicted graphically below, the cut guide is positioned "generally adjacent at least a portion of the anterior side . . . and the medial side" (first positioning limitation) and also "generally medially" (second positioning limitation). Additionally, the resection is performed by "guiding a cutting tool . . . from . . . the medial . . . side of the knee" (first guiding limitation) and "includes cutting a lateral side of the tibia" (second guiding limitation).



If the claim is properly construed as a medial side cutting approach that cuts into the lateral side, even the Board acknowledged that Samuelson teaches that "the surgeon's blade passes the midline of the bone" and a "part of the opposite side is cut into." A26. Thus, the Board did not contend that Samuelson teaches the surgeon stopping a medial side cutting approach at exactly the midline of the knee and Samuelson cannot be read as disclosing such a precise and implausible surgical technique. Rather, as shown in the figure above, any cut from one side will necessarily extend across the midline at least some minimal amount and into the other side. Accordingly, Samuelson's one-sided cutting approach necessarily includes a cut into the other side.

b. Two-Sided Cutting Approach

In Samuelson's Two-Sided Cutting Approach, when one of both arms are deployed, the cut guide is positioned "generally adjacent at least a portion of the anterior side . . . and the medial side [and] lateral side" (first positioning limitation). Also, when only the medial arm is positioned against the medial side of the knee before the lateral side arm is positioned, the cut guide is also positioned "generally medially" (second positioning limitation). When one or both arms are deployed, the resection is performed by "guiding a cutting tool . . . from . . . at least one of the medial side or lateral side of the knee" (first guiding limitation) and "includes cutting a lateral side of the tibia" (second guiding limitation). Thus, the Two-Sided Cutting Approach anticipates the claims.

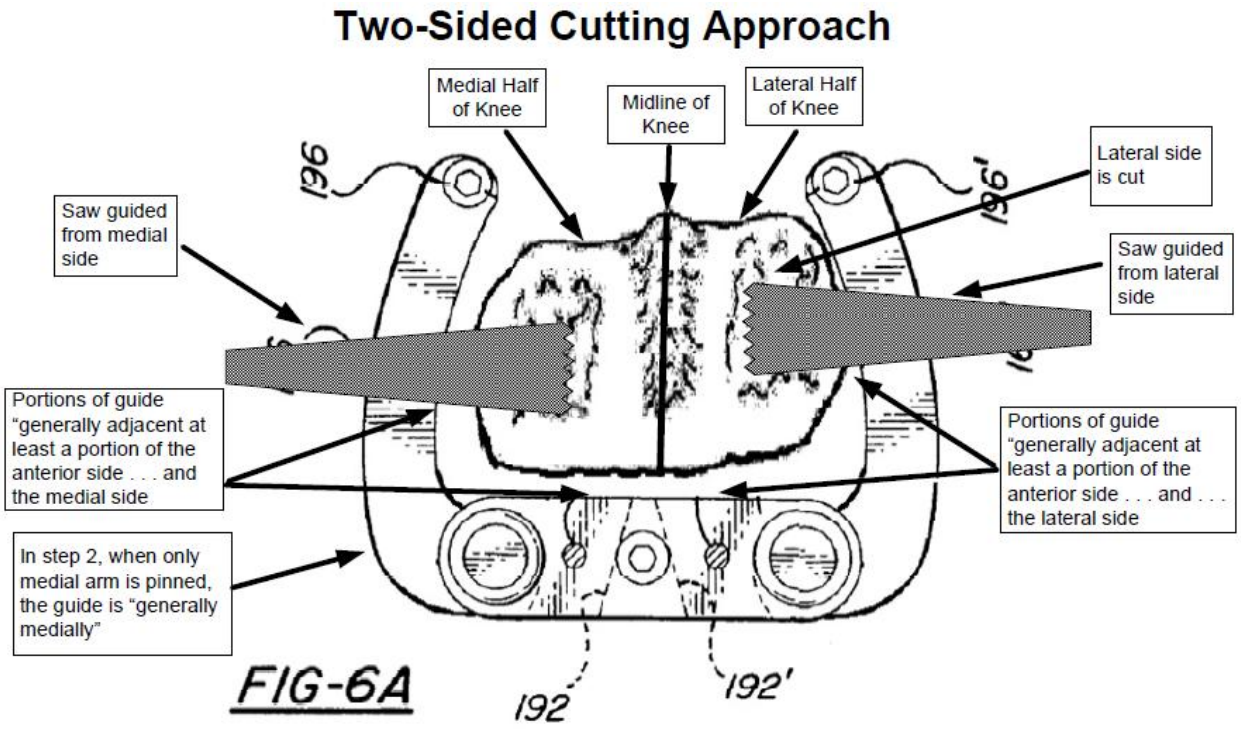


FIG-6A

2. Amended Claims 31, 33, 45, and 47

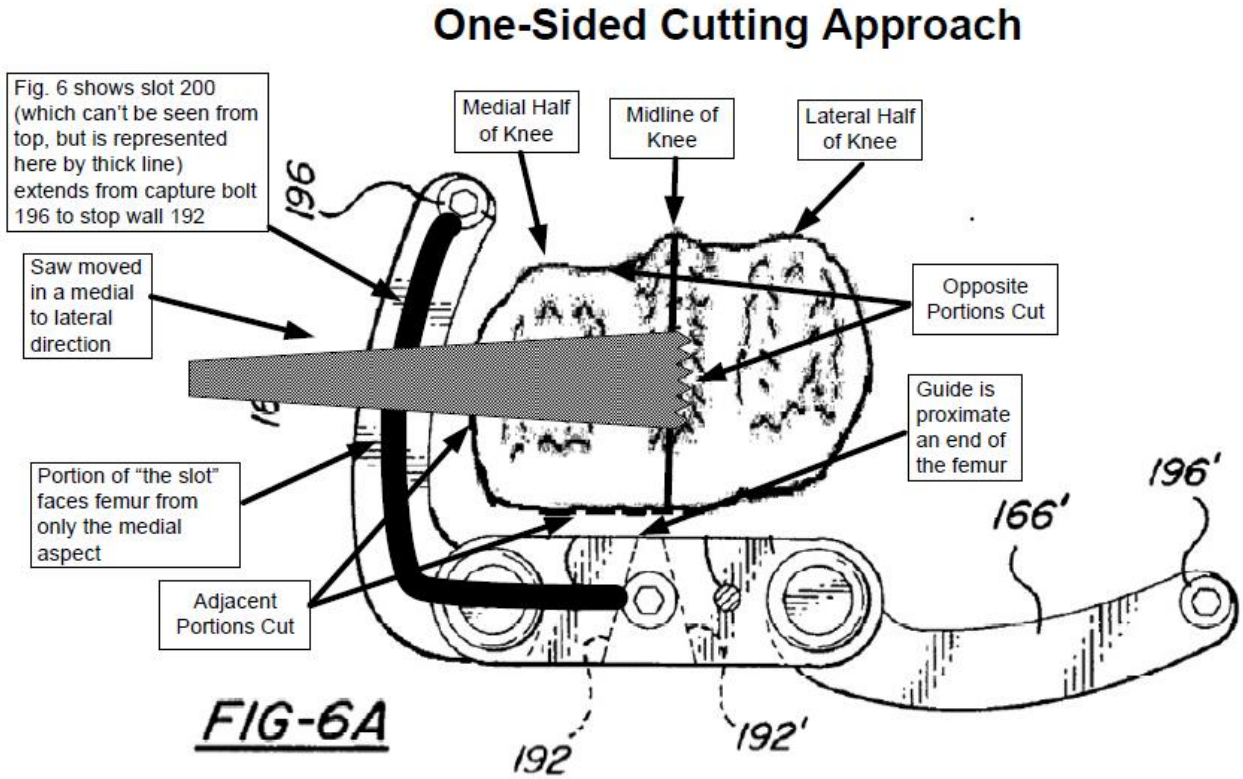
Claim 31 includes the following four relevant limitations:

> (1) "positioning the cutting guide [which has a slot] in a position proximate an end of one of a femur or a tibia";
>
> (2) "at least a portion of the slot facing the end of the one of the femur or the tibia from only one of a medial aspect or a lateral aspect with no other portion of the slot positioned along the other of the medial aspect or the lateral aspect";
>
> (3) "cutting the end of the one of the femur or tibia by moving the cutting tool in . . . at least one of a medial to lateral direction or a lateral to medial direction to create at least a portion of at least one resected surface"; and
>
> (4) "plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion . . . adjacent to the position of the cutting guide and a medial portion of a lateral portion . . . across from and opposite to the position of the cutting guide."

a. One-Sided Cutting Approach

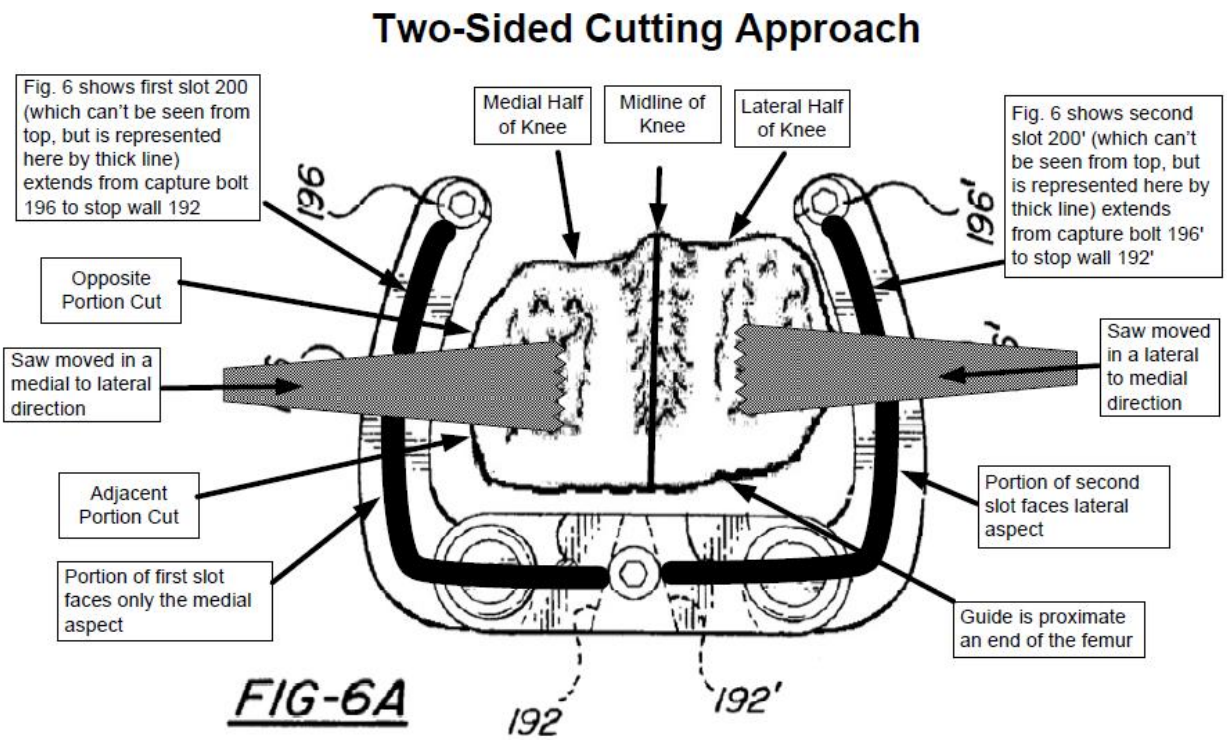
In the One-Sided Cutting Approach, a cut guide with a slot is positioned "proximate an end of one of a femur or a tibia" (first positioning limitation) such that "at least a portion of the slot fac[es] , . . . only [the] medial aspect . . . [and] no other portion of the slot positioned along the . . . the lateral aspect" (second positioning limitation). The resection is performed by "moving the cutting tool in . . . a medial to lateral direction" (first guiding limitation) by "plunging the saw blade through the slot to create the resected surface on both [1] medial portion[s] . . . adjacent to the position of the cutting guide and [2] a medial portion [and] a lateral portion . . . across from and opposite to the position of the cutting guide"

(second guiding limitation). As explained above (*see* Section II(B)(2)), under a proper construction the portions of the bone cut include (1) the medial half of the anterior side of the knee, which is adjacent to the anterior portion of the cutting guide, and (2) the medial half of the posterior side of the knee, which is across from and opposite to the position of the anterior portion of the cutting guide. Additionally, because any cut from the medial side necessarily crosses over the midline of the knee and into the lateral side, a cut from the medial side also includes (1) a portion of the medial side, which is adjacent to the medial arm of the cutting guide, and (2) a portion of the lateral side, which is across from and opposite to the medial arm of the cutting guide.



b. Two-Sided Cutting Approach

In the Samuelson Two-Sided Cutting Approach, a cut guide with a slot is positioned "proximate an end of one of a femur or a tibia" (first positioning limitation) such that "at least a portion of the slot fac[es] . . . only [the] medial aspect . . . [and] no other portion of the slot positioned along the . . . the lateral aspect" (second positioning limitation). This is true even though *a different* slot 200' may face the lateral aspect. When one or both arms are deployed, the resection is performed by "moving the cutting tool in . . . a medial to lateral direction [and] a lateral to medial direction" (first guiding limitation) by "plunging the saw blade through the slot to create the resected surface on both [1] a medial portion . . . adjacent to the position of the cutting guide and [2] a medial portion . . . across from and opposite to the position of the cutting guide" (second guiding limitation). For example, the portions of the bone cut include (1) a portion of the medial side that is adjacent to the medial arm of the cutting guide and (2) a portion of the medial side that is across from and opposite to the lateral arm of the cutting guide. Of course, like the Samuelson one-sided cutting approach, in the two-sided approach, a cut from one side will in all likelihood pass the midline and thus cut portions on both sides of the knee.



3. Amended Claims 39, 40, 53, and 54

Claim 39 includes the following four relevant limitations:

(1) "positioning the femoral cutting guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee";

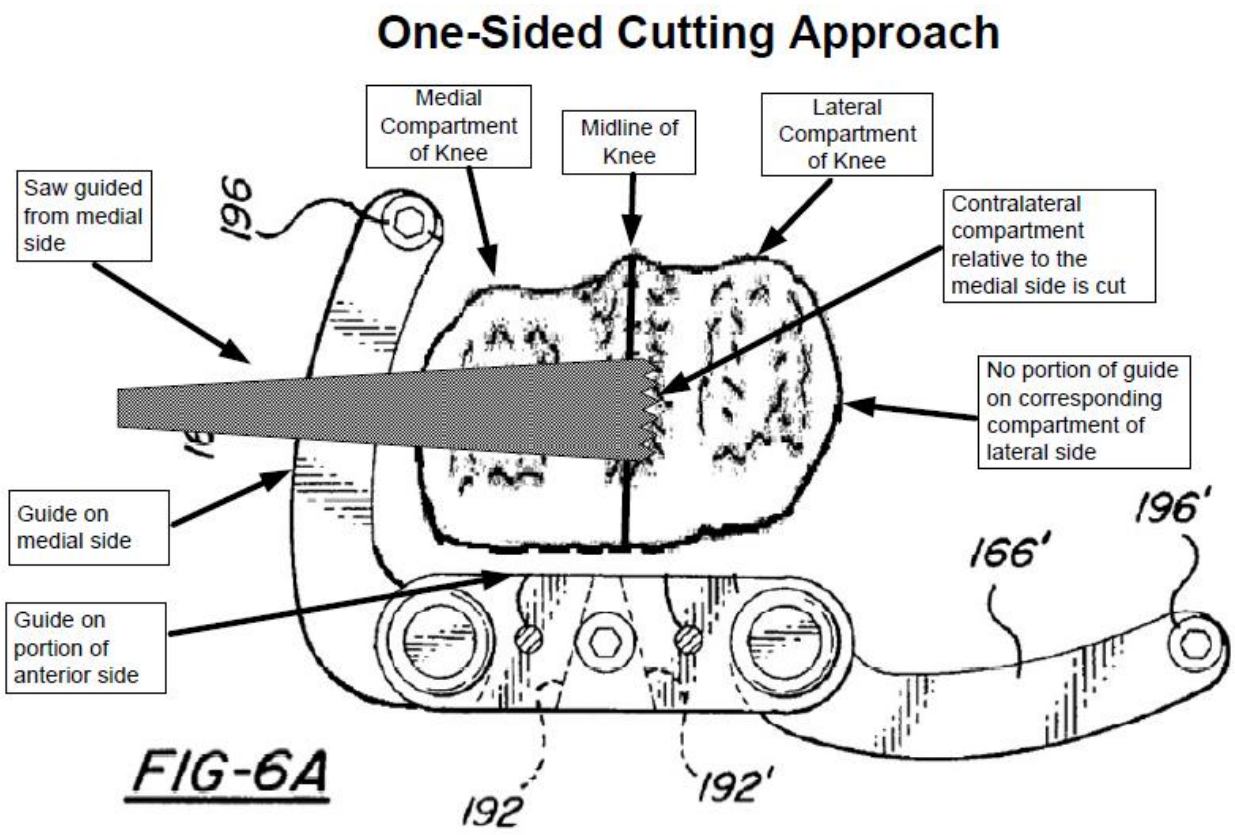
(2) "positioning the femoral cut guide positions the femoral cut guide to extend toward and generally along only one of the medial side or the lateral side of the knee with no portion of the femoral cut guide positioned along the other of a corresponding compartment of the medial side or the lateral side of the femur";

(3) "using the femoral cut guide to create at least one resected surface on the distal end of the femur by guiding the long axis of the saw blade from the one of the medial side or the lateral side of the knee"; and

(4) "cutting a contralateral compartment relative to the one of the medial side or the lateral side of the femur."

a. One-Sided Cutting Approach

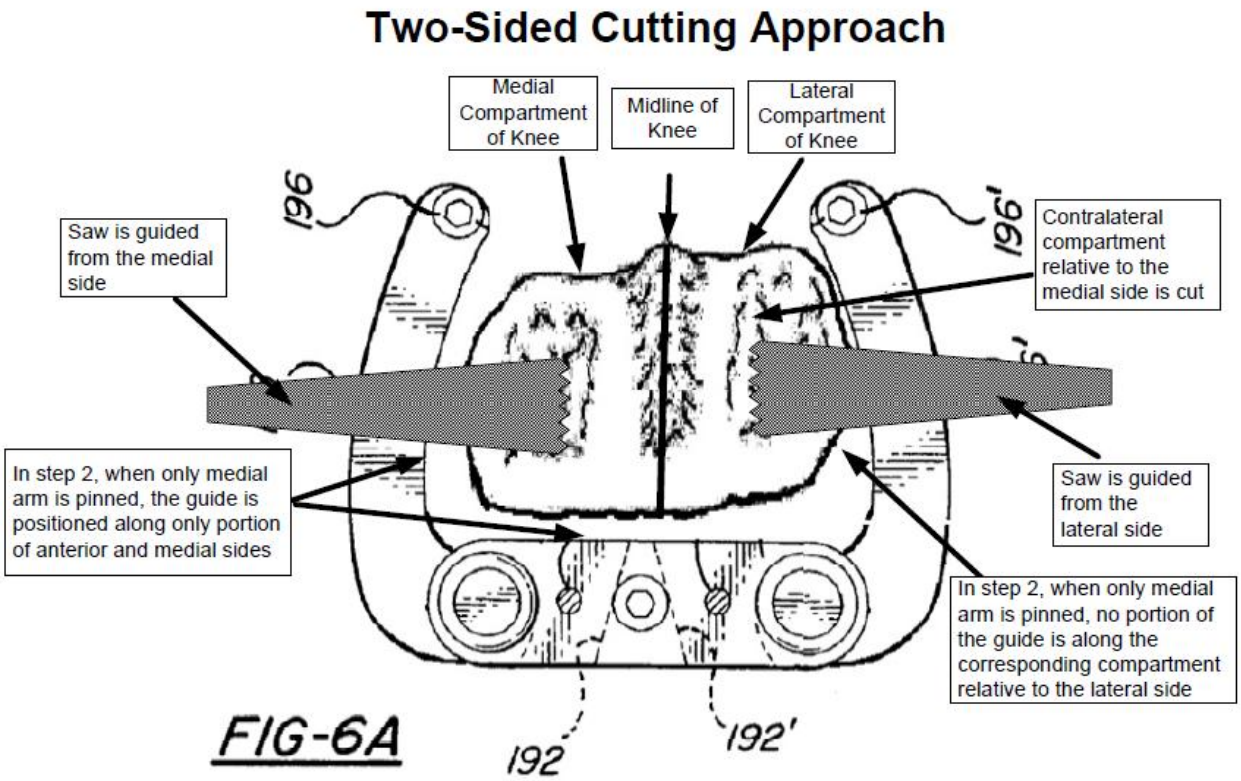
In the One-Sided Cutting Approach, a cut guide is positioned "toward and generally along only a portion of an anterior side of the femur and . . . a medial side . . . of the knee" (first positioning limitation) "with no portion of the femoral cut guide positioned along the . . . corresponding compartment of the . . . the lateral side of the femur" (second positioning limitation). The resection is performed by "guiding the long axis of the saw blade from . . . the medial side . . . of the knee" (first guiding limitation) and includes "cutting a contralateral compartment relative to . . . the medial side . . . of the femur" (second guiding limitation). Indeed, as discussed above (*see* section III(A)(1)(a)), cutting from the medial side will necessarily involve cutting across the midline into a contralateral compartment relative to the medial side of the femur.



b. Two-Sided Cutting Approach

In the second step of the Samuelson Two-Sided Cutting Approach (where only the medial arm of the cut guide is positioned against the knee), a cut guide is positioned "toward and generally along only a portion of an anterior side of the femur and . . . a medial side . . . of the knee" (first positioning limitation) "with no portion of the femoral cut guide positioned along the . . . corresponding compartment of the . . . the lateral side of the femur" (second positioning limitation). In the third step (resection from the medial side), the resection is performed by "guiding the long axis of the saw blade from . . . the medial side . . . of the knee" (first guiding limitation), and the fifth step (resection from the lateral

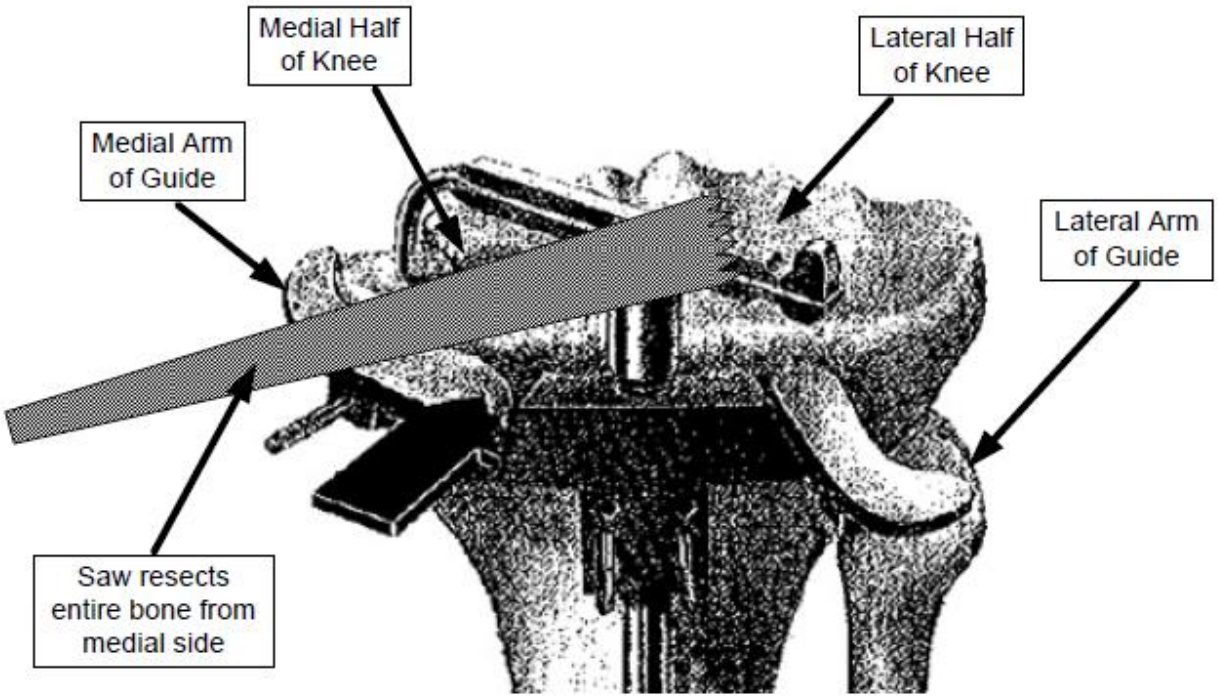
side) includes "cutting a contralateral compartment relative to . . . the medial side . . . of the femur" (second guiding limitation).



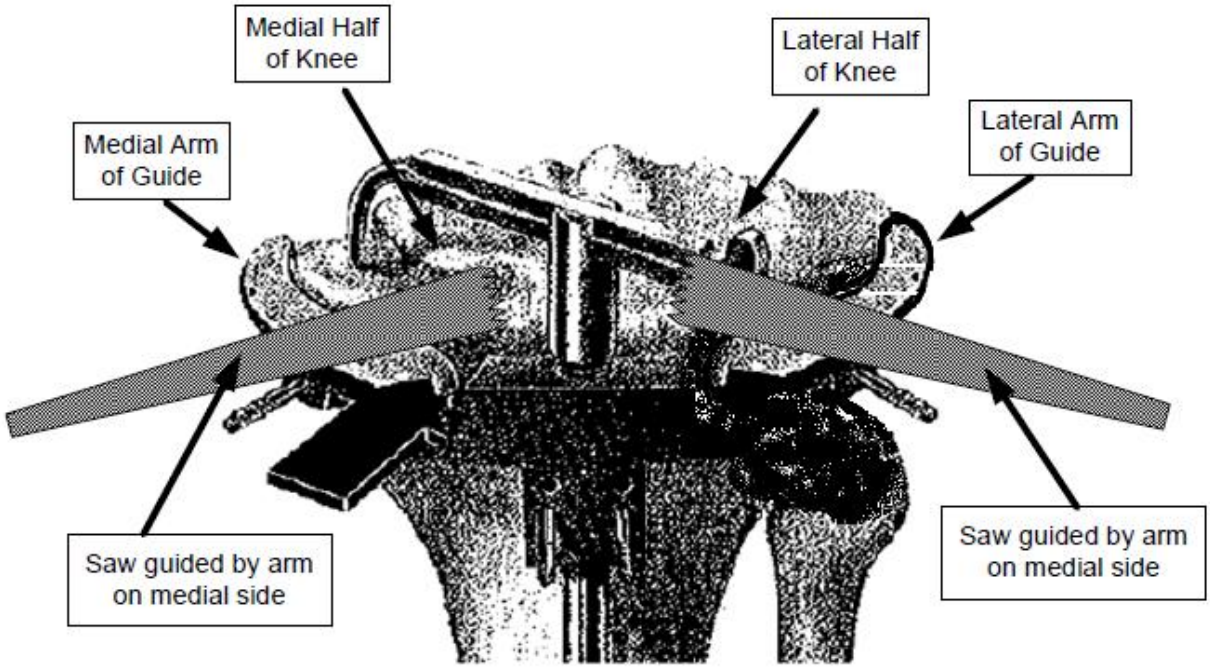
B. Protek Anticipates All Claims Under Their Proper Construction

Protek teaches One-Sided and Two-Sided Cutting Approaches that are substantially similar to those of Samuelson. A2300-01, A2307. Accordingly, the Allowed Claims are anticipated by Protek for the same reasons discussed above with regard to Samuelson.

Protek's One-Sided Cutting Approach



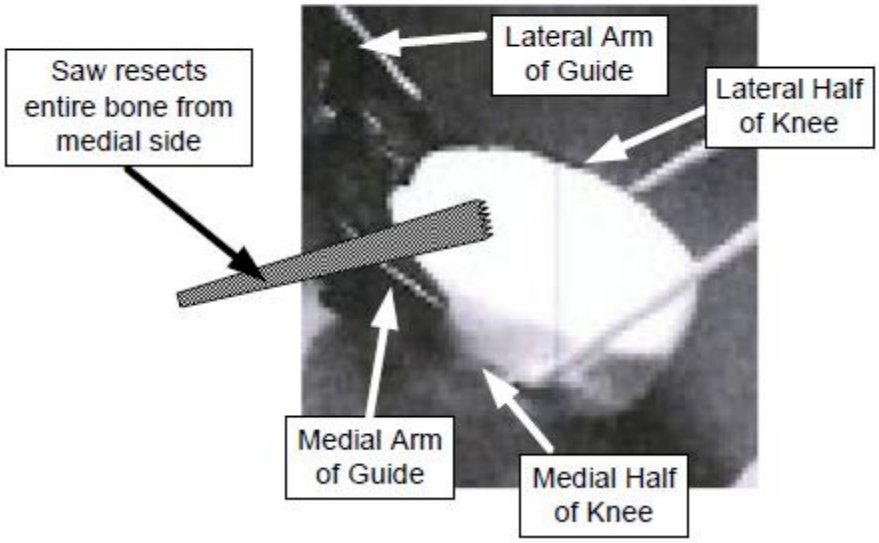
Protek's Two-Sided Cutting Approach

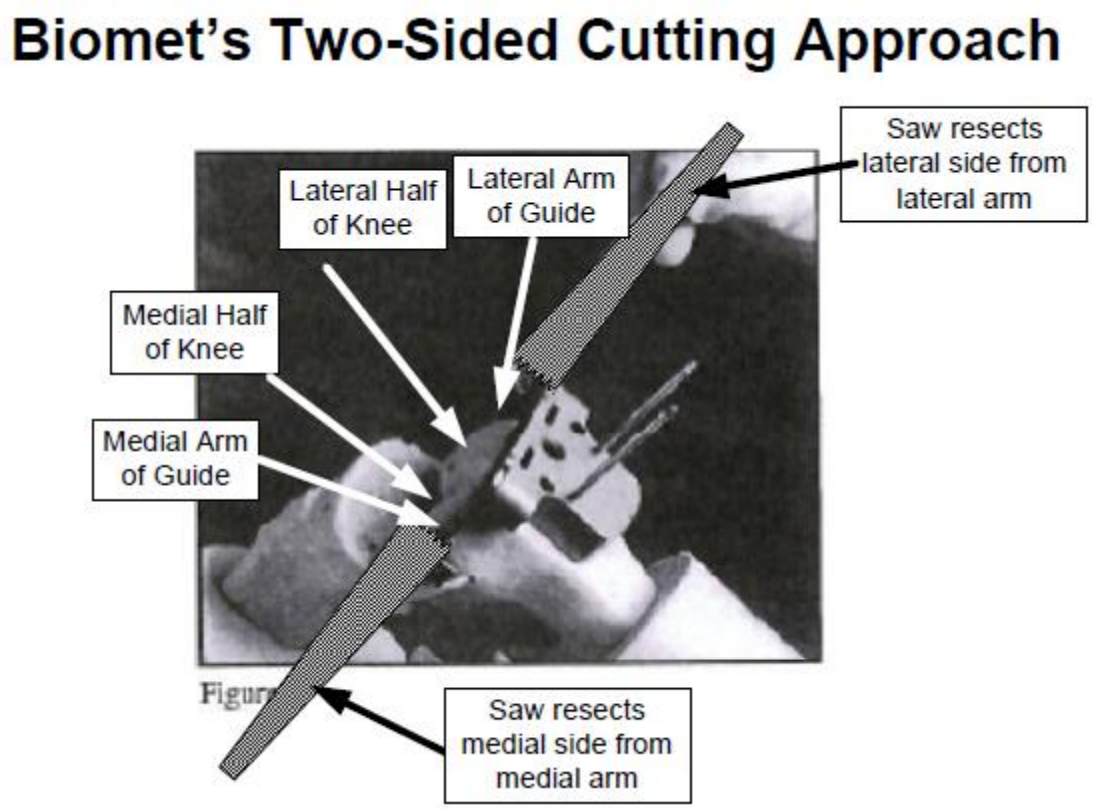


C. Biomet Anticipates All Claims Under Their Proper Construction

Similarly, Biomet teaches One-Sided and Two-Sided Cutting Approaches that are substantially similar to those of Samuelson. A2205, A2208. Accordingly, the Allowed Claims are anticipated by Biomet for the same reasons discussed above with regard to Samuelson.

Biomet's One-Sided Cutting Approach





D. Even Under the Board's Improper Claim Constructions, the Allowed Claims are Invalid As the Prior Art Teaches a Complete Resection from Only One Side

1. Biomet

Biomet teaches a complete resection of the tibia using a cutting guide with only a single swing arm, i.e., the medial swing arm, in the deployed position. Specifically, in Figure 19, the "tibial resection guide[] is centered on the front of the tibia" and one arm of the guide is shown pinned to the medial side of the tibia. A2207-08. Biomet states, "[b]ecause of the position of the patellar tendon it is not possible to use the cutting guide arm on the lateral side," and "the proximal tibia is cut along the cut block." A2208. Biomet expressly teaches the use of a cut guide

positioned along a portion of the anterior side and using only one of the medial or lateral sides to completely resect the proximal end of the tibia. Accordingly, even under the Board's improper claim construction, the Allowed Claims are invalid as anticipated by Biomet.

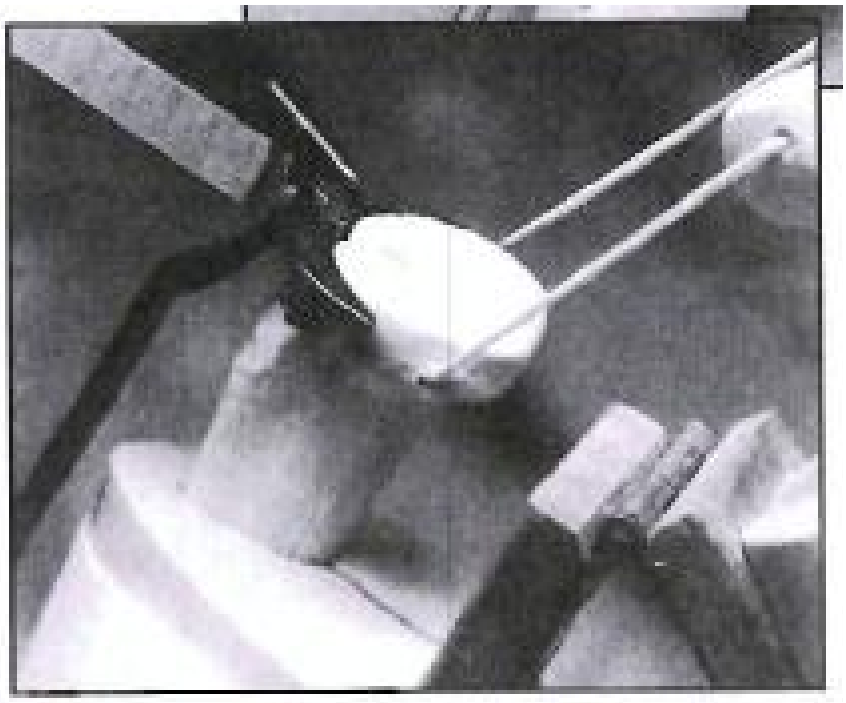
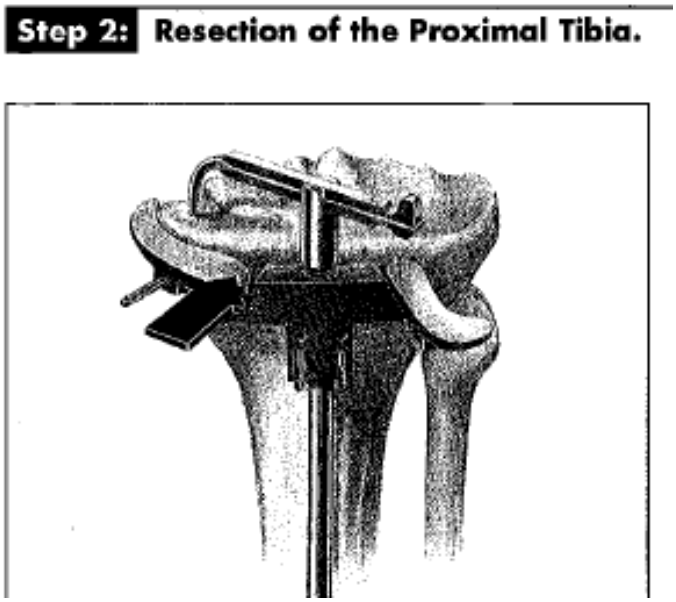


Figure 19

2. Protek

Like Biomet, Protek also teaches a complete resection of the tibia using a cut guide with only a single swing arm deployed along the medial side of the knee (*see* figure below). The tibial resection is performed using a "Tibia cutting guide" "centered on the front of the tibia," which includes moveable "arms that wrap around the tibia medially." A2297. Although the guide includes two arms, Protek teaches that only the medial arm of the cutting guide is placed around the knee and

used for resection. As in Biomet, "[b]ecause of the position of the patellar tendon it is not possible to use the cutting guide arm on the lateral side." A2297. Once the guide is positioned along a portion of the anterior side of the knee and the medial side of the knee, "the proximal tibia is cut along the top surface of the guide," which would include a cut to the lateral side using a guide on the medial side. A2297. Accordingly, even under the Board's improper claim construction, the Allowed Claims are invalid as anticipated by Protek.



3. Samuelson

While Samuelson teaches a cutting guide with both medial and lateral swing arms, only one of those swing arms is disclosed as performing the resection. When describing the femoral cut guide of Fig. 6 (A2176), Samuelson expressly states that "the surgeon resects the distal end of the femur 26 by using a bone saw (not shown) through the slot 200." A2185. The description of the tibial cut guide of

Fig. 11 is similar. A2187. These statements expressly teach the entire bone—not just one of the sides—is resected using only one arm of the cutting guide. Samuelson could have disclosed that "the surgeon resects one side of the femur proximate the slot 200 using a bone saw (not shown) through the slot 200," but there is no such disclosure. Samuelson says the surgeon uses a single slot in a single swing arm to resect "the distal end of the femur," which includes the medial and lateral sides of the femur. A2185.

Samuelson also claims a one swing arm embodiment to resect a bone in Claim 10 which recites the steps of:

> (1) providing a "guide body" (i.e., cut guide) with a "laterally extending member" (swing arm);
>
> (2) "moving said laterally extending member [so that] said laterally extending member is located adjacent to the bone";
>
> (3) "inserting the blade through said [slot in the swing arm]"; and
>
> (4) "resecting the bone by movement of the blade of the saw."

A2187.

The Board thus erred when it said "Samuelson teaches a medial cutting guide to cut the medial side of the bone and a lateral cutting guide to cut the lateral side, but nowhere explicitly discloses a single guide placed on one side or the other and used to cut into the other." A9. In alleging that

Samuelson requires the use of both the medial and lateral swing arms for a resection, the Board did not cite Samuelson but relied on Hudson's brief:

> as Patent Owner states, "by the express teachings of Samuelson, when the reference discusses positioning the medial swing arms 334 and 360 around the tibia and utilize[s] the medial slot 370 to resect the tibia, the lateral swing arms 334', 360' and slot 370' are also used in the same exact manner when the bone is resected."

A9. Samuelson, however, contains no such teaching. The language in Samuelson relied on by Hudson states:

> As the description above with respect to the assembly 140, only one of any two like components of the subassemblies 286 and 284 will be discussed, although both the discussed component as well as its primed counterpart are generally shown in several figures. It is again to be understood that discussion of the one will apply equally to the primed component not discussed.

A2186. This passage merely indicates that one swing arm (component) is structurally symmetrical to the other swing arm (primed counterpart). Indeed, the passage is prefaced with the phrase "with respect to the assembly 140, only one of two like components . . . will be discussed" (A2186), indicating a desire to prevent duplicative discussion of the assembly itself – not the method of resection.

Samuelson never states that both swing arms and slots are required for a resection. Its method uses only one side for the resection as it discloses that "the surgeon resects the distal end of the femur 26 by using a bone saw (not shown) through the slot 200" on the medial swing arm. A2185. If Samuelson's statement

that "discussion of the one will apply equally to the primed component not discussed" applied to the method of resection, it would merely indicate that if the resection uses the other swing arm 166', then the corresponding slot 200' of that arm would be used in the same way that the corresponding slot 200 is used with swing arm 166. In either case, however, a complete resection still would be performed using only a single arm.

For at least these reasons, even under the Board's improper claim construction, all claims are invalid as anticipated by Samuelson.

4. Samuelson in View of Protek

Even if Samuelson is read as requiring the use of both swing arms, based on Protek it would have been obvious to a person skilled in the art to use only a single swing arm of the Samuelson cut guides to perform a resection. Protek's figure on page 18 and corresponding language makes clear that using a single swing arm to resect the entire bone is both possible and desirable. A229. Further, Protek states that although two moveable swing arms are available it is desirable for a surgeon to use only one swing arm when tendons, such as the patellar tendon, interfere with the ability to use the other swing arm. A2297. Protek teaches a person skilled in the art that either movable swing arm in Samuelson is capable of performing a complete resection and further provides an express motivation (avoiding the patellar tendon) to use only a single swing arm. Accordingly, even under the

Board's improper claim construction, all claims are invalid as obvious over the combination of Samuelson and Protek.

E. The Unamended Claims Are Based On the Open-Ended Language of Original Independent Claim 13, which the Board Found was Unpatentable Even After Amendment

In an attempt to overcome the prior art during reexamination, Hudson amended its claims to remove several open-ended limitations. A2810-51. In its April 22, 2011 amendments, however, while Hudson made narrowing amendments to original Claim 13, newly independent Claim 35 was not amended.[15]

Amended Claim 13	Original Claim 35
positioning the tibial cut guide generally adjacent [at least] **only** a portion of an anterior side of the tibia	positioning the tibial cut guide generally adjacent **at least a** portion of an anterior side of the tibia
and [at least] **only one of** the medial side or the lateral side of the knee; and	and **at least one of** the medial side or the lateral side of the knee;
from [at least] **the one** of the medial side or the lateral side of the knee	from **at least one of** the medial side or the lateral side of the knee

As shown in the chart above, the limitations of amended Claim 13 are narrower than the corresponding limitations of unamended Claim 35. The Board affirmed that Claim 13, even after these narrowing amendments, was not

[15] Hudson also did not amend the other Unamended Claims 36-38 and 49-52. A2832-39, A2841-50. The only change to these claims was rewriting the former dependent claim into dependent form. A2830-32.

patentable over Samuelson. A11-12. Further, the only additional limitations in Claim 35 that are not recited in Claim 13 are that (1) the positioning step "locates the tibial cut guide generally medially," and (2) the guiding/cutting step "includes cutting a lateral side of the tibia." The prior art's disclosure of these limitations was not disputed by the Board. For example, Protek discloses positioning a cut guide that is "generally medially," and, because the entire proximal end of the tibia is resected, the lateral side of the tibia was necessarily cut. Accordingly, because the Board found the prior art anticipated the narrower Claim 13, it necessarily should have also found that the same prior art also anticipated Claim 35. The Board erred by failing to do so.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Biomet requests that this Court reverse the Board's claim constructions for Claims 31, 33, 35-40, 45, 47, and 49-54 and reverse the Board's decision finding that those claims are valid.

Dated: May 18, 2015

Respectfully submitted,

/s/ Douglas D. Salyers

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ADDENDUM

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMET ORTHOPEDICS, LLC and
BIOMET MANUFACTURING CORPORATION
Third Party Requester, Cross-Appellant

v.

HUDSON SURGICAL DESIGN, INC.
Patent Owner, Appellant

Appeal 2014-001731
Reexamination Control 95/001,469
US Patent No. 7,344,541 B2[1]
Technology Center 3900

Before: STEVEN D.A. McCARTHY, DANIEL S. SONG, and BRETT C. MARTIN, *Administrative Patent Judges*.

MARTIN, *Administrative Patent Judge*.

DECISION ON APPEAL

---

[1] Issued to Haines et al. on March 18, 2008 (hereinafter referred to as "the '541 patent").

STATEMENT OF THE CASE

Patent Owner/Appellant appeals under 35 U.S.C. §§ 134(b) and 315 from the Examiner's rejection of claims 1-54. Third Party Requester/Cross-Appellant appeals under 35 U.S.C. §§ 134(c) and 315, the non-adoption of the proposed rejection of certain claims as anticipated by either Matsen or Ferrante as well as certain non-adopted indefiniteness rejections. We have jurisdiction under 35 U.S.C. §§ 134 and 315.

The '541 patent is currently involved in the following and past litigation proceedings (App. Br. 1):

Hudson Surgical Design, Inc. v. *Biomet Orthopedics, LLC and Biomet Manufacturing Corporation,* Case No. 3:10-CV-00465-PPS-CAN, N.D. Ind., stayed pending the result of the present reexamination;

Hudson Surgical Design, Inc. v. *Depuy Orthopaedics, Inc.,* Case No.3: 1 O-CV -00463-HD-CAN, N.D. Ind., stayed pending the result of the present reexamination;

Hudson Surgical Design, Inc. v. *Zimmer Holdings, Inc., Zimmer, Inc., Rush System for Health and Rush University Medical Center,* Civil Action No. 08 C 1566, N.D. Ill., dismissed with prejudice; and

Hudson Surgical Design, Inc. v. *Smith & Nephew, Inc.,* Case No. 2:2011cv01371, W.D. Wash., dismissed with prejudice.

Reexamination Control 95/002,152 was also filed on September 7, 2012 by Depuy Orthopaedics, Inc., against U.S. Patent No. 7,967,822, which is a continuation of and claims priority to the '541 patent. App. Br. 2.

We AFFIRM-IN-PART.

THE INVENTION

Patent Owner's invention is directed generally to "methods and apparatus for femoral and tibial resection to allow for the interconnection or attachment of various prosthetic devices." Spec. col. 1, ll. 34-36. Claim 1, reproduced below with bracketing and underlining to show amendments made during reexamination prosecution, is illustrative of the claimed subject matter:

> 1. A method for a knee arthroplasty procedure comprising:
>
> positioning at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is positioned along only one of a medial side or a lateral side and proximate an end of a long bone of a knee joint with no other portion of the guide surface positioned along a corresponding compartment of the other of the medial side or the lateral side of the long bone, the at least one guide surface also being positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the [at least] one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;
>
> using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface on the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direction along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and
>
> implanting a knee arthroplasty implant on the at least one resected surface.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Woolson	US 4,841,975	Jun. 27, 1989
Matsen	US 4,979,949	Dec. 25, 1990
Ferrante	US 5,364,401	Nov. 15, 1994
Samuelson	US 5,611,802	Mar. 18, 1997

Freeman Samuelson Total Knee System Brochure by Biomet, Inc. ("Biomet") (1994)

Mark II Total Knee Replacement System by Protek ("Mark II") (1985)

F/S Modular Total Knee Replacement System by Protek ("Protek") (1991)

THE REJECTIONS ON APPEAL

The Examiner made the following rejections:

1. Claims 1-29, 31-43, and 45-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Samuelson. RAN 10, 11.

2. Claims 1-29, 31-43, and 45-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Samuelson and Protek. *Id.*

3. Claims 1-12, 21-25, 28-33, and 42-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Samuelson and Matsen. *Id.*

4. Claims 1-29, 31-43, and 45-54 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Biomet. *Id.*

5. Claims 1-5, 8, 21, and 22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mark II. *Id.*

6. Claims 1-29, 31-43, and 45-54 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Protek. *Id.*

7. Claims 1-3, 5-12, 21-25, 28-33, and 42-47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Woolson. *Id.*

8. Claims 5, 13-20, 26, 39, 53, and 54 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. RAN 20-21.

9. Claims 1-4, 6-8, 21, and 23 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. RAN 21-22

ANALYSIS

Claim Construction

Patent Owner first challenges the Examiner's claim construction as failing to consider alleged past disavowals and improperly interpreting amended claim language to cover references over which the claim was originally allowed. *See* App. Br. 11-13. We first note that one purpose of reexamination is to correct previous examiner error, including errors in claim construction. The mere fact that a construction during reexamination covers such prior art is not dispositive because claim construction may be the error that the reexamination corrects. We therefore are not persuaded that a new construction that encompasses past prior art is improper.

Patent Owner argues that the statement, "Bert et al. shows the slot facing the end of both the medial and lateral aspects, whereas claim 43 (issued as claim 9) requires the slot to face only one of a medial or a lateral aspect," from the original prosecution amounts to a clear disavowal. App. Br. 13-14 (emphasis removed). This statement, however, refers only to a single slot and does not reference a guide surface, which is what is claimed.

Further, in Bert, there are multiple slots depicted (122 and 123), and it is not entirely clear whether the statement in the original prosecution somehow referred to both slots (plural) or just one of the two slots. Also, given the present Examiner's decision to divide tools like that shown in Bert into two halves, the alleged disavowal would be irrelevant because the Examiner considers the medial side to be the claimed "at least one guide surface," while the opposing lateral side would not be limited by the claims as currently written. Ultimately, it is unclear from this single statement that the type of disavowal suggested by Patent Owner was actually made.

Additionally, as noted above, the disavowal to which Patent Owner points was only to claim 43 (which issued as claim 9), and its dependent claim 46, and further accompanied an amendment unrelated to the alleged disavowal. It is unclear whether it was the amendment or the statement, again unrelated to the amended language, that convinced the Examiner to allow the claims. Accordingly, we do not agree that this is the type of clear disavowal necessary to limit claim construction as applied to all claims presently before us.

Turning to the claim language itself, claim 1 recites "positioning at least one generally planar cutting guide surface…." While the claim then further limits placement of the claimed at least one generally planar cutting guide surface, the presence of "at least one" allows for the presence of additional cutting guide surfaces that would not be subject to those same limitations. As the Examiner states, "'the at least one guide surface,' 'the cutting guide,' etc. as recited in the claims can be defined by only a portion of one of the guides of Samuelson." RAN 12. The claims as currently

written limit only the claimed guide surface and do not preclude other guide surfaces as are found in Samuelson. This is a reasonable interpretation of the claims.

Anticipation by Samuelson

Claims 35-38 and 49-52

Patent Owner argues that regardless of construction, these claims are not anticipated because Samuelson does not disclose using a medial- or lateral-placed guide to cut from that side to the other side using only the single guide. App. Br. 15. The claim limitation at issue states, "wherein positioning the tibial cut guide locates the tibial cut guide generally *medially* and…further includes cutting a *lateral* side of the tibia." Claim 35 (emphasis added). Patent Owner notes that "[t]here is simply no teaching or suggestion in Samuelson that the blade is extended from the medial or lateral side of the tibia all the way through to the opposite side." App. Br. 16-17.

We agree because as Patent Owner states, "by the express teachings of Samuelson, when the reference discusses positioning the medial swing arms 334 and 360 around the tibia and utilize[s] the medial slot 370 to resect the tibia, the lateral swing arms 334', 360' and slot 370' are also used in the same exact manner when the bone is resected." App. Br. 16. In other words, Samuelson teaches a medial cutting guide to cut the medial side of the bone and a lateral cutting guide to cut the lateral side, but nowhere explicitly discloses a single guide placed on one side or the other and used to cut into the other side (i.e., from the lateral into the medial side or vice versa), for example as in claim 35.

Third Party Requester ("Requester") asserts that Samuelson specifically teaches using one swing arm to perform a resection, but we do not agree that the portion cited by Requester clearly states that this is the case. *See* Requester's Resp. Br. 7-8. In referring to the operation of the swing arms 200 and 200', we agree with Patent Owner that the description appears only to describe cutting the portion of the bone on the same side as the swing arm and subsequently using the opposite guide to cut the opposite side. Regardless, we do not find this disclosure to be sufficiently explicit to support an anticipation rejection and do not sustain the Examiner's rejection of claims 35-38 and 49-52 as anticipated by Samuelson.

Claims 1-4, 6-8, 21, and 23

Patent Owner argues claims 1-4, 6-8, 21, and 23 as a group. We select claim 1 as representative. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2011). Patent Owner argues that even discounting swing arm 334' so that there is no swing arm positioned along the lateral side of the bone, "the cutting guide slot 361 extends along the entire anterior (or front) face of the bone" in contradiction with the claim language requiring "no other portion of the guide surface positioned along a corresponding compartment of the other of the medial side or the lateral side" of the bone. App. Br. 17-18.

We disagree with this assertion because it is not commensurate with the scope of the claims as construed by the Examiner. The Examiner utilizes swing arm 334 to meet the language of "at least one generally planar guide surface." The fact that guide portion 361 does not satisfy this limitation is of no moment because the rest of the claim applies only to the recited "at least one guide surface," which is swing arm 334, not slot 361. As noted above

with respect to claim construction, the claims as written allow for other guide surfaces that may be placed anywhere on the bone. In order not to satisfy the claim language, Patent Owner needs to show that swing arm 334 is positioned along something other than the medial side of the bone, which it has not done. Accordingly, we sustain the Examiner's rejection of claims 1-4, 6-8, 21, and 23 as anticipated by Samuelson.

Claims 5 and 22

Patent Owner makes essentially the same argument as above in reference to claims 5 and 22 by relying on its claim construction and asserting the slot 361 "extends along the entire anterior face of the bone and, as such, extends along greater than one-half of a width of the anterior side." App. Br. 20. As with claim 1, the Examiner does not use slot 361 to meet the claim language, but only uses slot 200, which meets the claim language. Accordingly we sustain the Examiner's rejection of claims 5 and 22 as anticipated by Samuelson.

Claims 9-12, 24, 25, 27-29, 34, 41-43, and 48

Patent Owner reasserts the arguments presented above with respect to claims 5 and 22, which we have already rejected. App. Br. 21. Again, Patent Owner points to portions of Samuelson that are not used by the Examiner to meet the claim limitations at issue. As such, we sustain the Examiner's rejection of claims 9-12, 24, 25, 27-29, 34, 41-43, and 48 as anticipated by Samuelson.

Claims 13-15, 17, 18, and 26

As above, Patent Owner makes arguments that are not commensurate with the scope of these claims or the rejection made by the Examiner. For

the same reasons as stated *supra*, we sustain the Examiner's rejection of claims 13-15, 17, 18, and 26 as anticipated by Samuelson.

Claims 16, 19, 31-33, 39, 40, 45-47, 53, and 54

Patent Owner essentially restates arguments made with respect to the independent claims from which these claims depend. App. Br. 22-23. Having already rejected these arguments, we sustain the Examiner's rejection of these claims as anticipated by Samuelson.

Anticipation by Woolson

Having already sustained the Examiner's rejection of most of the claims subject to the rejections over Woolson as anticipated by Samuelson, we need not address the cumulative rejection of these claims over Woolson. Claims 30 and 44, however, do not stand rejected as anticipated by Samuelson, but are rejected as anticipated by Woolson.

In general, Patent Owner argues the rejections over Woolson under the same rationale as that with respect to Samuelson, namely that the Examiner improperly relies on aspects of Woolson that extend along both lateral and medial aspects. *See* App. Br. 34-37. As with Samuelson, however, these aspects to which Patent Owner points are in addition to the portions the Examiner uses to meet the claim language at issue. As noted above, the claims are not so narrow as to preclude the presence of other guide surfaces and so we are not persuaded generally as to the asserted error in the rejections over Woolson. Patent Owner also makes no specific argument relating to claims 30 and 44 and so we have no basis to reverse the Examiner specifically with regard to these two claims. As such we affirm

the Examiner's decision to reject claims 30 and 44 as anticipated by Woolson.

Anticipation by Biomet

Claims 35-38 and 49-52

As with Samuelson, above, we agree with Patent Owner that Biomet fails to teach cutting all the way across the bone utilizing the cutting guide positioned on one side. As Patent Owner states, "Biomet expressly states that both arms, plural, are used to resect the femur." App. Br. 24. For the same reasons as stated above with respect to Samuelson, we do not sustain the Examiner's rejection of claims 35-38 and 49-52.

Remaining Claims

Having already sustained the Examiner's rejection of claims 1-29, 31-34, 39-43, and 45-54 as anticipated by Samuelson, we need not address the cumulative rejection of these claims over Biomet.

Anticipation by Protek F/S Modular

Claims 35-38 and 49-52

As with Samuelson and Biomet, above, we agree with Patent Owner that Protek fails to teach cutting all the way across the bone utilizing the cutting guide positioned on one side. As Patent Owner states, "[t]here is no express teaching in Protek F/S Modular that the lateral side of the tibia is actually cut from the medial side guide surface, rather than the anterior guide surface." App. Br. 30. For the same reasons as stated above with respect to

Samuelson and Biomet, we do not sustain the Examiner's rejection of claims 35-38 and 49-52.

Remaining Claims

Having already sustained the Examiner's rejection of the remaining claims as anticipated by Samuelson, we need not address the cumulative rejection of these claims over Protek.

Obviousness over Samuelson and Protek F/S Modular

Having already sustained the Examiner's rejections above as anticipated by Samuelson as to some of the claims, we need not reach the cumulative rejections over the combination of Samuelson and Protek as to those claims. Regarding claims 35-38 and 49-52, having already determined that neither of Samuelson nor Protek teaches the pertinent limitations of these claims, it follows that the combination cannot make up for these deficiencies. Accordingly we do not sustain the Examiner's rejection of claims 35-38 and 49-52 as unpatentable over Samuelson and Protek.

Obviousness over Samuelson and Matsen

Having already sustained the Examiner's rejection of the claims subject to the rejections over the combination of Samuelson and Matsen as anticipated by Samuelson or Woolson, we need not address the cumulative rejection of these claims over Samuelson and Matsen.

Non-Adopted Rejections

Requester appeals the Examiner's non-adoption of anticipation rejections over each of Matsen and Ferrante. Because these rejections deal

with claims that were rejected and sustained as anticipated by Samuelson or Woolson, we will not address the non-adoption due to their cumulative nature.

Indefiniteness/Written-Description Rejections

Claim 5

Patent Owner argues that the Examiner has misconstrued the claims, as well as that the language at issue is original language and cannot properly be rejected under 35 U.S.C. § 112 during reexamination. *See* App. Br. 40-41. Patent Owner further argues that the claims are fully supported as shown at least in Figure 18. *Id.* We agree with Patent Owner on all counts and thus do not sustain the Examiner's written description rejection of claim 5.

Claims 13, 16, and 26

The Examiner asserts that these claims lack written description because the '541 patent discloses the cutting guide of Figure 18 as being used only with the tibia and not the femur. *See* RAN 21. As Patent Owner correctly argues, however, these claims are sufficiently supported by adequate written description by way of the fact that the Specification explains how the cutting guide is useful for avoiding the problem of quad tendon interference. *See* App. Br. 42. Because the quad tendon interacts only with the femur, we agree with Patent Owner that the Specification sufficiently supports the device being used with either the femur or the tibia. Accordingly, we do not sustain the written description rejections of these claims.

Claims 1-4, 6-8, 21, and 23

As the Patent Owner points out, the Examiner rejects these claims "as being indefinite for using the phrase 'corresponding compartment,' stating that there was no antecedent basis for use of the word 'corresponding.'" App. Br. 43. The claim language at issue is "with no other portion of the guide surface positioned along a corresponding compartment of the other of the medial or lateral side of the long bone." Because this language refers to "a" corresponding compartment and we are persuaded by Patent Owner's assertion that one of skill in the art would understand that "it is inherent that a 'corresponding compartment' of either the medial or lateral side refers to either the medial compartment or the lateral compartment, respectively," we agree that the claim language is not indefinite. App. Br. 44. Furthermore, because we agree that one of ordinary skill in the art would understand what is meant by the lateral and medial compartments, we conclude that there is no lack of written description as suggested by Requester. Requester App. Br. 19. Accordingly, we do not sustain the Examiner's rejection of claims 1-4, 6-8, 21, and 23 for lack of antecedent basis.

Claims 9, 10, 24, and 25

Requester appeals the Examiner's decision not to adopt proposed indefiniteness rejections because the claim terms at issue, "medial aspect" and "lateral aspect," are original claim language and therefore not subject to review under 35 U.S.C. § 112. We agree with the Examiner that this language is non-reviewable in this reexamination. Requester further argues that the Examiner failed to properly consider the newly added negative limitation regarding "no other portion of the slot positioned along the other

of the medial aspect or the lateral aspect." Requester App. Br. 20, 22. We are not persuaded by Requester's argument that Figure 18 is insufficient to support this limitation. Regardless of whether there is a distinct boundary, we conclude that the disclosure is sufficiently clear to support that the cutting guide is only on one of the medial or lateral aspects, but not on the other.

Claims 5 and 22

Likewise, we agree with the Examiner that the rejection relating to "at least a portion" was properly not adopted because such language is original. Regarding claim 22, Requester further argues that there is insufficient support for there being "only two portions." Requester App. Br. 21, 24. Again, we conclude that Figure 18, as explained by Patent Owner, sufficiently supports the pertinent recitations regarding the two portions and one of skill in the art would understand the claim language at issue. Accordingly, we agree with the Examiner's decision not to reject claims 5 and 22 as indefinite.

Claims 13 and 26

The Examiner chose not to adopt Requester's proposed rejection of claims 13 and 26 "because the phrase 'positioning the femoral cut guide to extend toward and generally along only a portion of the anterior side of the femur and only one of a medial side or a lateral side of the knee' can be understood by one of ordinary skill in the art." RAN 23. For the reasons stated by the Examiner in the RAN, we agree that one of skill in the art would understand the language and therefore sustain the Examiner's decision not to adopt Requester's proposed rejection.

DECISION

For the above reasons, we AFFIRM the Examiner's decision to reject claims 1-29, 31-34, 39-43, 45-48, 53, and 54 as anticipated by Samuelson and claims 30 and 44 as anticipated by Woolson. We REVERSE the Examiner's decision to reject claims 35-38 and 49-52 as anticipated by any of Samuelson, Biomet, and Protek as well as the all of the Examiner's rejections under 35 U.S.C. § 112. We also AFFIRM the Examiner's non-adoption of the various rejections under 35 U.S.C. § 112.

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. §§ 1.956 and 41.77(g).

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED-IN-PART

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Appeal 2014-001731
Reexamination Control 95/001,469
US Patent No. 7,344,541 B2

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95/001,469	10/15/2010	7344541	BIOMET1	7743

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REIP, DAVID OWEN

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMET ORTHOPEDICS, LLC and
BIOMET MANUFACTURING CORPORATION
Third Party Requester, Cross-Appellant

v.

HUDSON SURGICAL DESIGN, INC.
Patent Owner, Appellant

Appeal 2014-001731
Reexamination Control 95/001,469
US Patent No. 7,344,541 B2[1]
Technology Center 3900

Before: STEVEN D.A. McCARTHY, DANIEL S. SONG, and BRETT C. MARTIN, *Administrative Patent Judges*.

MARTIN, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

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[1] Issued to Haines et al. on March 18, 2008 (hereinafter referred to as "the '541 patent").

STATEMENT OF THE CASE

The Third Party Requester ("Requester") and the Patent Owner ("PO") each filed a Request for Rehearing (hereinafter "Req's. Rhrg. Req." and "PO's Rhrg. Req.," respectively) under 37 C.F.R. § 41.79 seeking rehearing of our Decision mailed April 30, 2014 (hereinafter "Decision" or "Dec."), which affirmed-in-part various rejections by the Examiner. The Requester asserts that the Board overlooked various points and requests modification of the Decision relating to claims 35-38 and 49-52. Req's. Rhrg. Req., cover page. The Patent Owner asserts that the Board overlooked various points and requests modification of the Decision relating to dependent claims 31, 33, 39, 40, 45, 47, 53, and 54. PO's Rhrg. Req. 1.

We grant Requester's Rehearing Request to the extent that we consider the Requester's arguments *infra*, but DENY the request to modify the Decision. We GRANT the Patent Owner's Rehearing Request and amend our original Decision to REVERSE the Examiner's decision to reject claims 31, 33, 39, 40, 45, 47, 53, and 54.

Requester's Rehearing Request

Requester asserts that the Board "misapprehended or overlooked certain limitations of Claims 35-38 and 49-52 that it found patentable." Req's. Rhrg. Req. 1. Requester's next sentence belies this alleged misapprehension and/or overlooking by stating that "the Board improperly found that these claims require 'a single guide placed on one side or the other and used to cut into the other side (i.e., from the lateral side into the medial side or vice versa).'" *Id.*, citing Dec. 8. This argument implies disagreement with the Board's claim interpretation, not misapprehension by the Board.

First, the portion of a sentence quoted by the Requester does not completely convey the Board's claim construction. The Decision makes clear, by way of the affirmed rejections, that the claims do not preclude additional guides or guide surfaces. *See* Dec. 7. It is only the language of the claims subject to the reversed rejections that specifically requires using a single guide to cut into the other side. The "single guide" language above is not meant to limit the claims to the presence of a single guide, but merely to the use of that guide to cut both sides.

Second, Requester's statement amounts to mere disagreement with the Board's Decision rather than meeting the standard that something was misapprehended or overlooked. In fact, the Board explained in the Decision why it accepted the Patent Owner's construction and rejected the Requester's position (Dec. 8-9). In its Rehearing Request, the Requester merely restates its original arguments. Contrary to Requester's assertion, the Board directly dealt with the issues raised in Requester's Rehearing Request. The result was simply not the one argued for by Requester. This is not a proper use of a Rehearing Request and is merely an attempt to have the Board reconsider its previous Decision. Accordingly, we deny Requester's Rehearing Request to the extent that the Rehearing Request asks us to modify the original Decision.

Patent Owner's Rehearing Request

Unlike Requester, the Patent Owner points to an actual instance of the Board overlooking arguments. As the Patent Owner notes, the Board sustained the rejection of dependent claims 31, 33, 39, 40, 45, 47, 53, and 54, among others, because of an understanding that the Patent Owner merely

argued the rejections of these claims in a fashion similar to that in which the Patent Owner unsuccessfully argued the rejections of the independent claims from which these claims ultimately depend. PO's Rhrg. Req. 3. The Patent Owner states that it did argue the aforementioned dependent claims for different reasons, namely that the claims should be allowable for the same reasons as claims 35-38 and 49-52. *Id.* Patent Owner specifically points out that these arguments were made in Patent Owner's Rebuttal Brief at page 7. *Id.* We note that the Patent Owner also made these arguments in its opening brief. *See* PO's App. Br. 22-23. Accordingly, Patent Owner has made a proper showing that the Board overlooked pertinent arguments relating to the claims at issue.

Turning to the merits of Patent Owner's arguments, each of the claims at issue recites similar, and in some cases identical, language further limiting the various independent claims from which they depend (31 from 9, 33 from 32, 39 from 16, 40 from 19, 45 from 24, 47 from 46, 53 from 26, and 54 from 26). Each of the dependent claims at issue recites language that conveys that the cut guide is used on one side of the bone to cut the other side as part of the resection in the same way that we determined was the case for claims 35-38 and 40-52 in our original decision.

Requester disagrees and asserts, for example, with respect to claim 31, its independent claim, claim 9, "only limits the position of 'the slot' such that 'at least a portion of **the slot**…fac[es] the end of the… femur…."' Requester's Comments on PO's Rhrg. Req. 3. Requester goes on to assert that claim 31 "does not mean that both a medial portion **and** a lateral portion of the knee be cut." *Id* at 5. We disagree. Claim 31 specifically recites

"plunging the saw blade through *the slot* to create the resected surface on *both* a medial portion or[2] a lateral portion" (emphasis added), i.e., this language cannot refer to other portions of the cutting guide as is the case with the independent claim, but requires the cut through both sides to be made through the same slot regardless of what other slots may be present as allowed by the broader claim 9.

Requester, with respect to claim 39, also asserts that the claim language "does not require 'both **sides**' of the knee be cut" and that the Patent Owner "misrepresents that the claim requires a 'contralateral **side**' to be cut." Requester's Comments on PO's Rhrg. Req. 9. Requester attempts to assert that a side is different from a compartment and that because there are three compartments – medial, central, and lateral – that the claims could include cutting into the central compartment. *Id.* Again, we disagree. The context of claim 39 describes cutting a contralateral compartment "relative to the one of the medial side or the lateral side of the femur." We think this language is clear that the contralateral compartment is not merely any compartment besides the lateral compartment, but that it is the opposite or "contra" compartment, which would be the medial compartment in relation to the lateral compartment or vice versa. As such, we agree with the Patent Owner that we should have reversed the Examiner's rejection as to claim 39 and the other claims with similar language.

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[2] Although the claim recites "both" and "or" here, which may appear confusing, we understand this language to refer to the fact that, in claim 9, one of the medial *or* lateral sides is originally cut. Claim 31 then adds that the other, which was not originally cut, is also cut using the same slot. So, the "or" is attempting to convey that the other of what was not cut in claim 9 is now also cut, while also that both the medial and lateral sides are cut.

Requester further argues that "[a]nother problem with the Owner's description of Samuelson is that in order for a two-sided surgical resection to not invalidate these claims, a surgeon would need to stop cutting from each side at exactly the midline of the knee." Requester's Comments on PO's Rhrg. Req. 12. We disagree. In construing the claims, the claim language as a whole must be interpreted in light of the Specification, not simply looking at each phrase in a vacuum and divorced from the Specification. *See e.g., In re NTP*, 654 F. 3d 1279, 1288 (Fed. Cir. 2011). With regard to claims 35-38 and 49-52 as well as the claims at issue in this rehearing, we construe them as referring to the resection of the bone and not just the specific portion being cut. When taking the claims at issue in context, it is not merely the fact that the surgeon's blade passes the midline of the bone, but that the entire resection is being done using a guide on one side to complete the resection.

Even if part of the opposite side is cut into (but not in a manner that completes the resection) as argued by the Requester, the surgeon must still remove the blade and complete the resection using a different cutting guide. We think the claims at issue sufficiently convey that, in each instance, the resection is completed by using a single cut guide to cut from one side to the other. In other words, the Patent Owner's claims describe a complete resection, whereas the Requester's proposition that cutting into the other side falls within the scope of the claims only describes a partial resection that must then be completed using a different cutting guide, which is not the same as what is claimed. We think this distinction is made clear in each of dependent claims 31, 33, 39, 40, 45, 47, 53, and 54 and thus are persuaded

that we should have also reversed the rejections of these claims for the same or similar reasons as we reversed the rejections of claims 35-38 and 49-52.

REHEARING DECISION

We have considered the Decision in light of the Requests for Rehearing. As explained above, Requester's basis for requesting rehearing is not based upon anything misapprehended or overlooked, but amounts to an explanation as to why Requester disagrees with the Board's Decision, which is not a proper use for Requests for Rehearing. Patent Owner, however, has shown that the language recited in each of the claims at issue is of a similar nature as that in claims 35-38 and 49-52 and thus we revise our original decision to add reversal of the Examiner's rejections of claims 31, 33, 39, 40, 45, 47, 53, and 54 as requested by the Patent Owner.

Pursuant to 37 C.F.R. § 41.79(d), this Decision is final for the purpose of judicial review. A party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

GRANTED as to PATENT OWNER, DENIED as to REQUESTER.

Appeal 2014-001731
Reexamination Control 95/001,469
US Patent No. 7,344,541 B2

alw

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EXAMINER	
REIP, DAVID OWEN	

ART UNIT	PAPER NUMBER
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CENTRAL REEXAMINATION UNIT

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Transmittal of Communication to Third Party Requester
Inter Partes Reexamination

REEXAMINATION CONTROL NO. : 95001469
PATENT NO. : 7344541
TECHNOLOGY CENTER : 3999
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified Reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

PTOL-2070(Rev.07-04)

ORDER GRANTING/DENYING REQUEST FOR* INTER PARTES *REEXAMINATION	**Control No.** 95/001,469	**Patent Under Reexamination** 7344541	
	Examiner David O. Reip	**Art Unit** 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

The request for *inter partes* reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): ☐ PTO-892 ☒ PTO/SB/08 ☐ Other: _____

1. ☒ The request for *inter partes* reexamination is GRANTED.

☐ An Office action is attached with this order.

☒ An Office action will follow in due course.

2. ☐ The request for *inter partes* reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 312(c). Requester may seek review of a denial by petition to the Director of the USPTO within ONE MONTH from the mailing date hereof. 37 CFR 1.927. EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183. In due course, a refund under 37 CFR 1.26(c) will be made to requester.

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Order.

DECISION ON REQUEST FOR INTER PARTES REEXAMINATION

A substantial new question of patentability affecting claims 1-54 of United States Patent Number 7,344,541 ("the '541 patent") is raised by the request for *inter partes* reexamination.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving the '541 patent throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

The third party requester ("3PR") relies on the following references:

- U.S. Pat. No. 5,611,802 to Samuelson et al ("Samuelson")
- *Freeman Samuelson Total Knee System*, published by Biomet, Inc., 1994 ("Biomet Brochure")
- *Mark II Total Knee Replacement System*, published in 1985 ("Mark II")
- *Protek F/S Modular Total Knee Replacement System*, published by Protek in January 1991 ("Protek F/S Modular")
- U.S. Pat. No. 4,979,949 to Matsen et al ("Matsen")
- U.S. Pat. No. 5,364,401 to Ferrante et al. ("Ferrante")
- U.S. Pat. No. 4,841,975 to Woolson et al ("Woolson")

The request indicates that the 3PR considers:

(1) Samuelson presents a substantial new question of patentability ("SNQ") with regard to claims 1-54 of the '541 patent.

(2) Biomet Brochure presents an SNQ with regard to claims 1-54 of the '541 patent.

(3) Mark II presents an SNQ with regard to claims 1-5, 8, 21 and 22 of the '541 patent.

(4) Protek F/S Modular presents an SNQ with regard to claims 1-54 of the '541 patent.

(5) Matsen presents an SNQ with regard to claims 1-12, 21-25, 28-33 and 42-47 of the '541 patent.

(6) Ferrante presents an SNQ with regard to claims 1-12, 21-25, 27-34 and 41-48 of the '541 patent.

(7) Woolson presents an SNQ with regard to claims 1, 2, 4-12, 21-25, 27-34 and 41-48 of the '541 patent.

The 3PR proposes the following grounds of rejection (see 3PR's Table of Contents, pages iv-xi):

Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson.

Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular.

Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen.

Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102 as being anticipated by Biomet Brochure.

Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II.

Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular.

Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen.

Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferrante.

Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson.

Samuelson

It is agreed that the consideration of Samuelson raises an SNQ as to claims 1-54 of the '541 patent. Request pages 31-34, section V(A), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Samuelson was not fully appreciated in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Samuelson raises an SNQ as to claims 1-54, which question has not been decided in a previous examination of the '541 patent.

Biomet Brochure

It is agreed that the consideration of the Biomet Brochure raises an SNQ as to claims 1-54 of the '541 patent. Request pages 34-35, section V(B), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in the Biomet Brochure was not present in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, the Biomet Brochure raises an SNQ as to claims 1-54, which question has not been decided in a previous examination of the '541 patent.

Mark II

It is agreed that the consideration of Mark II raises an SNQ as to claims 1-5, 8, 21 and 22 of the '541 patent. Request pages 36-37, section V(C), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Mark II was not present in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Mark II raises an SNQ as to claims 1-5, 8, 21 and 22, which question has not been decided in a previous examination of the '541 patent.

Protek F/S Modular

It is agreed that the consideration of Protek F/S Modular raises an SNQ as to claims 1-54 of the '541 patent. Request pages 38-39, section V(D), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Protek F/S Modular was not present in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Protek F/S Modular raises an SNQ as to claims 1-54, which question has not been decided in a previous examination of the '541 patent.

Matsen

It is agreed that the consideration of Matsen raises an SNQ as to claims 1-12, 21-25, 28-33 and 42-47 of the '541 patent. Request pages 40-42, section V(E), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Matsen was not present in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Matsen raises an SNQ as to claims 1-12, 21-25, 28-33 and 42-47, which question has not been decided in a previous examination of the '541 patent.

Ferrante

It is agreed that the consideration of Ferrante raises an SNQ as to claims 1-12, 21-25, 27-34 and 41-48 of the '541 patent. Request pages 42-44, section V(F), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Ferrante was not fully appreciated in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Ferrante raises an SNQ as to claims 1-54, which question has not been decided in a previous examination of the '541 patent.

Woolson

It is agreed that the consideration of Woolson raises an SNQ as to claims 1, 2, 4-12, 21-25, 27-34 and 41-48 of the '541 patent. Request pages 44-46, section V(G), is hereby incorporated by reference from the request for reexamination for the explanation of the teaching provided in Woolson was not fully appreciated in the prosecution of the application that became the '541 patent. Further, there is substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Woolson raises an SNQ as to claims 1, 2, 4-12, 21-25, 27-34 and 41-48, which question has not been decided in a previous examination of the '541 patent.

Conclusion

For the reasons given above, each of the references cited by the requester raises a substantial new question of patentability with respect to the subject patent. Accordingly, claims 1-54 of the subject patent will be reexamined.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Inter Partes* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Other useful telephone numbers:

Reexamination Practice	(571) 272-7703
Reexamination Facsimile Transmission No.	(571) 273-9900

David O. Reip
Primary Examiner
Central Reexamination Unit
(571) 272-4702

Conferee

Conferee

PTO/SB/08a (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	
Filing Date	15 October 2010
First Named Inventor	HAINES, Timothy G.
Art Unit	
Examiner Name	
Attorney Docket Number	BIOMET1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
DR	C	US- 5,021,056	06-04-1991	Hofmann, et al.	Attached as Exhibit C
DR	D	US- 5,234,433	08-10-1993	Bert et al.	Attached as Exhibit D
DR	E	US- 5,611,802	03-18-1997	Samuelson, et al.	Attached as Exhibit E
DR	I	US- 4,979,949	12-25-1990	Matsen, et al.	Attached as Exhibit I
DR	J	US- 5,364,401	11-15-1994	Ferrante, et al.	Attached as Exhibit J
DR	K	US- 4,841,975	06-27-1989	Woolson, et al.	Attached as Exhibit K
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	11/1/10

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	
Filing Date	15 October 2010
First Named Inventor	HAINES, Timothy G.
Art Unit	
Examiner Name	
Attorney Docket Number	BIOMET1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
DR	F	Freeman Samuelson Total Knee System, published by Biomet, Inc., 1994 ("Biomet Brochure") (Attached as Exhibit F)	
DR	G	Mark II Total Knee Replacement System, published in 1985 (Attached as Exhibit G)	
DR	H	Protek F/S Modular Total Knee Replacement System, published by Protek in January 1991 (Attached as Exhibit H)	

Examiner Signature		Date Considered	11/1/10

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Search Notes

Application/Control No.	Applicant(s)/Patent under Reexamination
95/001,469	7344541
Examiner	**Art Unit**
David O. Reip	3993

SEARCHED			
Class	Subclass	Date	Examiner
NONE			

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
NONE			

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
patent file reviewed	11/1/2010	DR

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,469	10/15/2010	7344541	BIOMET1	7743

7590 11/23/2010

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EXAMINER	
REIP, DAVID OWEN	

ART UNIT	PAPER NUMBER
3993	

MAIL DATE	DELIVERY MODE
11/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Troutman Sanders LLP
5200 Bank of America Plaza
600 Peachtree Street, N.E., Suite 5200
Atlanta, GA 30308-2216

Transmittal of Communication to Third Party Requester
Inter Partes Reexamination

REEXAMINATION CONTROL NUMBER *95/001,469*.

PATENT NUMBER *7,344,541*.

TECHNOLOGY CENTER *3999*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

OFFICE ACTION IN* INTER PARTES *REEXAMINATION	**Control No.** 95/001,469	**Patent Under Reexamination** 7344541	
	Examiner David O. Reip	**Art Unit** 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:
Patent Owner on _____
Third Party(ies) on _____

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Response:
2 MONTH(S) from the mailing date of this action. 37 CFR 1.945. EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.956.
For Third Party Requester's Comments on the Patent Owner Response:
30 DAYS from the date of service of any patent owner's response. 37 CFR 1.947. NO EXTENSIONS OF TIME ARE PERMITTED. 35 U.S.C. 314(b)(2).

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

This action is not an Action Closing Prosecution under 37 CFR 1.949, nor is it a Right of Appeal Notice under 37 CFR 1.953.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892
2. ☐ Information Disclosure Citation, PTO/SB/08
3. ☐ _____

PART II. SUMMARY OF ACTION:

1a. ☒ Claims 1-54 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled.
3. ☐ Claims _____ are confirmed. [Unamended patent claims]
4. ☐ Claims _____ are patentable. [Amended or new claims]
5. ☒ Claims 1-54 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The drawings filed on _____ ☐ are acceptable ☐ are not acceptable.
8. ☐ The drawing correction request filed on _____ is: ☐ approved. ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has: ☐ been received. ☐ not been received. ☐ been filed in Application/Control No 95001469.
10. ☐ Other _____

Inter Partes Reexamination

The third party requester ("3PR") relies on the following references in the request for reexamination:

- U.S. Pat. No. 5,611,802 to Samuelson et al ("Samuelson")
- *Freeman Samuelson Total Knee System*, published by Biomet, Inc., 1994 ("Biomet Brochure")
- *Mark II Total Knee Replacement System*, published in 1985 ("Mark II")
- *Protek F/S Modular Total Knee Replacement System*, published by Protek in January 1991 ("Protek F/S Modular")
- U.S. Pat. No. 4,979,949 to Matsen et al ("Matsen")
- U.S. Pat. No. 5,364,401 to Ferrante et al. ("Ferrante")
- U.S. Pat. No. 4,841,975 to Woolson et al ("Woolson")

The 3PR proposes the following grounds of rejection (see 3PR's Table of Contents, pages iv-xi):

Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson.

Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular.

Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen.

Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102 as being anticipated by Biomet Brochure.

Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II.

Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular.

Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen.

Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferrante.

Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson.

Statutory Basis for Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Proposed Claim Rejections - Adopted and Adopted as Modified

As to Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-29, 31-43 and 45-54 is **adopted** for the reasons set forth in the request for reexamination, in claim chart A(1), pages 47-158, which is hereby incorporated by reference. The rejection of claim 30 is **not adopted** because Samuelson does not show the cutting guide as adjusting in at least flexion-extension and internal-external rotation, as required in the claim, and the rejection of claim 44 is **not adopted** for the same reason as claim 30.

As to Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-29, 31-43 and 45-54 is **adopted** for the reasons set forth in the request for reexamination, in claim chart A(2), pages 158-358, which is

hereby incorporated by reference. The rejection of claim 30 is **not adopted** because neither Samuelson nor Protek F/S Modular show a cutting guide that adjusts in at least flexion-extension and internal-external rotation, as required in the claim, and the rejection of claim 44 is **not adopted** for the same reason as claim 30.

As to Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted** for the reasons set forth in the request for reexamination, in claim chart A(3), pages 358-503, which is hereby incorporated by reference.

As to Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Biomet, assuming a June 7, 1995 priority date for the '541 patent claims, since the Biomet reference only gives "1994" as a copyright date. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-29, 31-43 and 45-54 is **adopted** for the reasons set forth in the request for reexamination, in claim chart B(1), pages 503-584, which is hereby incorporated by reference. The rejection of claim 30 is **not adopted** because Biomet does not show the cutting guide as adjusting in at least flexion-extension and internal-external rotation, as required in the claim, and the rejection of claim 44 is **not adopted** for the same reason as claim 30.

As to Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted** for the reasons set forth in the request for reexamination, in claim chart C(1), pages 584-602, which is hereby incorporated by reference.

As to Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-29, 31-43 and 45-54 is **adopted** for the reasons set forth in the request for reexamination, in claim chart D(1), pages 602-701, which is hereby incorporated by reference. The rejection of claim 30 is **not adopted** because Protek F/S Modular does not show the cutting guide as adjusting in at least flexion-extension and internal-external rotation, as required in the claim, and the rejection of claim 44 is **not adopted** for the same reason as claim 30.

As to Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted** for the reasons set forth in the request for reexamination, in claim chart E(1), pages 701-773, which is hereby incorporated by reference.

As to Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferrante. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-12, 21-25, 27-29, 31-34, 41-43 and 45-48 is **adopted** for the reasons set forth in the request for reexamination, in claim chart F(1), pages 773-829, which is hereby incorporated by reference. The rejection of claim 30 is **not adopted** because Ferrante does not show the cutting guide as adjusting in at least flexion-extension, as required in the claim, and the rejection of claim 44 is **not adopted** for the same reason as claim 30.

As to Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson. This rejection was proposed by 3PR in the request for reexamination, and it is **adopted as modified**, as follows: The rejection of claims 1-3, 5-12, 21-25, 28-33 and 42-47 is **adopted** for the reasons set forth in the request for reexamination, in claim chart G(1), pages 829-888, which is hereby incorporated by reference. The rejection of claim 4 is **not adopted** because the Woolson tibial guide of Figs. 8A-8B does not have all the limitations of claim 1 from which it depends, e.g. does not have medial or lateral portions. The rejection of claims 27 and 41 is **not adopted** because even assuming the "tacks" used in Woolson resemble nails or pins, they will not extend into the femur "from one of the medial aspect or lateral aspect" as claimed. The rejection of claims 34 and 48 is **not adopted** because even given 3PR's interpretation, once the block member 48 is tacked

to the femur ("when the cutting guide is connected in a predetermined location with respect to the long axis of the aperture"), the cutting guide 50 can translate up and down ("one translational degree of freedom") but does not have "one rotational degree of freedom" as recited in the claims.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,344,541 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise

the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

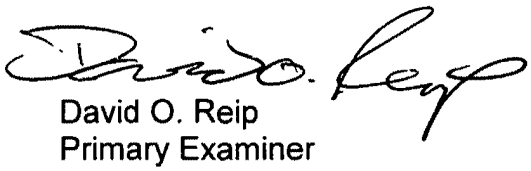
By **U.S. Postal Service Mail** to:

Mail Stop *Inter Partes* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

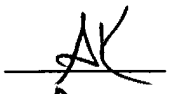
By FAX to: (571) 273-9900
Central Reexamination Unit

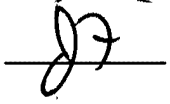
By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.



David O. Reip
Primary Examiner
Central Reexamination Unit
(571) 272-4702

Conferee 

Conferee 

Reexamination	Application/Control No.	Applicant(s)/Patent Under Reexamination
	95/001,469	7344541
	Certificate Date	Certificate Number

Requester Correspondence Address:	☐ Patent Owner	☒ Third Party

Troutman Sanders LLP
5200 Bank of America Plaza
600 Peachtree Street, N.E., Suite 5200
Atlanta, GA 30308-2216

LITIGATION REVIEW ☒	DOR (examiner initials)	10/20/10 (date)
Case Name		Director Initials
Hudson Surgical Design, Inc v. Biomet, Inc., 1:10cv4459, US-DIS-ILND, Status: OPEN.		
Hudson Surgical Design, Inc v. Depuy Orthpaedics, Inc, 1:10cv2103, US-DIS-ILND, Status: OPEN.		
Hudson Surgical Design, Inc v. Zimmer Holdings, Inc et al, 1:08cv1566, US-DIS-ILND, Status: CLOSED.		

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	NUMBER
1. None	
2.	
3.	
4.	

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,469	10/15/2010	7344541	BIOMET1	7743

7590 08/29/2011

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EXAMINER	
REIP, DAVID OWEN	

ART UNIT	PAPER NUMBER
3993	

MAIL DATE	DELIVERY MODE
08/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

TROUTMAN SANDERS LLP
5200 BANK OF AMERICA PLAZA
600 PEACHTREE STREET, N.E., SUITE 5200
ATLANTA, GA 30308-2216

Date:

MAILED

AUG 29 2011

CENTRAL REEXAMINATION UNIT

Transmittal of Communication to Third Party Requester
Inter Partes Reexamination

REEXAMINATION CONTROL NO. : 95001469
PATENT NO. : 7344541
TECHNOLOGY CENTER : 3999
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified Reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

PTOL-2070(Rev.07-04)

ACTION CLOSING PROSECUTION (37 CFR 1.949)	Control No.	Patent Under Reexamination
	95/001,469	7344541
	Examiner	Art Unit
	DAVID O. REIP	3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:
Patent Owner on 24 January 2011 AND 22 APRIL 2011
Third Party(ies) on 23 February 2011 AND 23 MAY 2011

Patent owner may once file a submission under 37 CFR 1.951(a) within 1 month(s) from the mailing date of this Office action. Where a submission is filed, third party requester may file responsive comments under 37 CFR 1.951(b) within 30-days (not extendable- 35 U.S.C. § 314(b)(2)) from the date of service of the initial submission on the requester. **Appeal cannot be taken from this action.** Appeal can only be taken from a Right of Appeal Notice under 37 CFR 1.953.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892
2. ☒ Information Disclosure Citation, PTO/SB/08
3. ☐ _____

PART II. SUMMARY OF ACTION:

1a. ☒ Claims 1-54 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled.
3. ☐ Claims _____ are confirmed. [Unamended patent claims]
4. ☐ Claims _____ are patentable. [Amended or new claims]
5. ☒ Claims 1-54 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The drawings filed on _____ ☐ are acceptable ☐ are not acceptable.
8 ☐ The drawing correction request filed on _____ is: ☐ approved. ☐ disapproved.
9 ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has: ☐ been received. ☐ not been received. ☐ been filed in Application/Control No _____
10. ☐ Other _____

Inter Partes Reexamination

Background

On 10/15/10, the request for *Inter Partes* reexamination of U.S. Pat. No. 7,344,541 was filed by the third party requester ("3PR").

On 11/10/10, the Decision granting reexamination was mailed.

On 11/23/10, a non-final Office action was mailed. All 54 patent claims were rejected on various grounds, as proposed by 3PR and adopted by the examiner.

On 1/24/11, patent owner ("PO") filed a timely response which included claim amendments. It was noted that the amendment did not comply with 37 CFR 1.530 and was therefore not entered.

On 2/23/11, 3PR filed Comments in response to PO's 1/24/11 response and amendment.

On 3/25/11, a Notice re Defective Paper in *Inter Partes* Reexamination was mailed wherein the defects in PO's 1/24/11 response and amendment were noted. PO was given 30-days or one month (whichever was longer) to file a corrected response and amendment.

On 4/22/11, PO filed a timely Response to Notice of Defective Paper. It is noted that PO's response included only a page 1 Transmittal notice, pages 2-43 of corrected claim amendments, and a page 44 "Status of claims and support for claim changes." PO did not resubmit their Remarks section. Therefore, the examiner has assumed PO's remarks are the same as those on pages 48-73 of PO's 1/24/11 response. With that

assumption, it is then noted that PO's complete response includes pages that are numbered 1-44 and 48-73, and that there are no pages numbered 45-47.

On 5/23/11, 3PR filed Comments in response to PO's response to Notice re Defective Paper.

Previous Prosecution

In the request, 3PR proposed the following grounds of rejection (see 3PR's Table of Contents, pages iv-xi):

Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson.

Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular.

Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen.

Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102 as being anticipated by Biomet Brochure.

Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II.

Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular.

Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen.

Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferrante.

Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson.

In the non-final Office action mailed 11/23/10, the examiner adopted all proposed rejections except the following:

As to Grounds A(1)(a) - A (1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds A(2)(a) - A(2)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds B(1)(a) - B(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds D(1)(a) - D(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds F(1)(a) - F(1)(o): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds G(1)(a) - G(1)(o): The proposed rejections of claims 4, 27, 34, 41 and 48 were not adopted.

PO's Amendment, 3PR's Response, and Examiner's decision

Grounds A(1)(a) - A(1)(s): PO arguments of paragraph A, pages 53-56 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Samuelson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(A), pages 13-20 have been considered. 3PR argues that Samuelson still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(A), pages 13-20 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Samuelson, e.g. as depicted in 3PR's Fig. 11A mark-up on p.15 of their Comments, wherein swing arm 334 along with arm support 352 defines "the guide surface." Thus, said "the guide surface," when placed in the operative position, would be generally along the medial or lateral side of the long bone being cut *with no other portion of the guide surface positioned along the corresponding compartment of the other of the medial side or the lateral side of the long bone*, as recited in e.g. amended claim 1.

Therefore, Grounds A(1)(a) - A(1)(s) are **sustained**.

Grounds A(2)(a) - A(2)(s) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para. IV(A), pages 43-45 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds A(3)(a) - A(3)(o) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para. IV(B), pages 45-46 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds B(1)(a) - B(1)(s): PO arguments of paragraph B, pages 56-59 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Biomet Brochure does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(B), pages 20-25 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(B), pages 20-25 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Biomet Brochure, e.g. as depicted in 3PR's drawings on p.22 of their Comments. Additionally, as argued by 3PR, Biomet Brochure at 18 expressly discloses placing only the medial cutting guide arm into the operative position because of the position of the patellar tendon.

Therefore, Grounds B(1)(a) - B(1)(s) are **sustained**.

Grounds C(1)(a) - C(1)(e): PO arguments of paragraph C, pages 59-61 have been considered. PO argues that the anticipation rejection of claims 1-5, 8, 21 and 22 should be withdrawn because Mark II does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(C), pages 25-28 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(C), pages 25-28 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the anterior view drawing at step 5 of the Proximal Tibia Osteotomy shows that with both cutting guide arms retracted, a portion of each arm is positioned along less than one-half a width of the anterior side. Also, as shown at step 7, the medial cutting guide arm is wrapped around the medial tibia and the tibia is saw cut in at least two directions -- 1) anterior to posterior, substantially perpendicular to a longitudinal axis of the anterior cutting guide; and 2) medial to lateral, substantially perpendicular to the curved axis of the medial cutting guide arm.

Therefore, Grounds C(1)(a) - C(1)(e) are **sustained**.

Grounds D(1)(a) - D(1)(s): PO arguments of paragraph D, pages 61-64 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Protek F/S Modular does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(D), pages 28-33 have been considered. 3PR argues that Protek F/S Modular still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(D), pages 28-33 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the Step 2: Resection of the Proximal Tibia on p. 18 of 57 expressly discloses wrapping only the medial cutting guide arm around the medial tibia because the position of the patellar tendon precludes the use of the cutting guide arm on the lateral side. Thus, for example with respect to claim 1, Protek F/S Modular shows "at least a portion of the at least one guide surface is positioned along only one of a medial side or a lateral side and proximate an end of a long bone of a knee joint with no other portion of the guide surface positioned along a corresponding compartment of the other of the medial side or the lateral side of the long bone" as recited.

Therefore, Grounds D(1)(a) - D(1)(s) are **sustained**.

Grounds E(1)(a) - E(1)(o): PO arguments of paragraph E, pages 64-66 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 28-33 and 42-47 should be withdrawn because Matsen does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(E), pages 34-37 have been considered. 3PR argues that Matsen still anticipates the claims as amended.

The examiner agrees with PO. While the Matsen guide as shown in Figs. 19-21 *could* be placed to cover the medial or lateral side of the bone and only a portion of the

anterior side as argued by 3PR, no explicit disclosure of such placement is made in Matsen. Thus, Matsen does not *anticipate* (i.e. expressly or inherently disclose) each and every method step as recited in the above listed claims as amended.

Therefore, Grounds E(1)(a) - E(1)(o) are **withdrawn**.

Grounds F(1)(a) - F(1)(o): PO arguments of paragraph F, pages 66-68 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 27-29, 31-34, 41-43 and 45-48 should be withdrawn because Ferrante does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(F), pages 38-40 have been considered. 3PR argues that Ferrante still anticipates the claims as amended.

The examiner agrees with PO, but not necessarily for the reasons as argued by PO. Upon reconsideration, the examiner notes that each independent claim previously held to be anticipated by Ferrante, i.e. claims 1, 5, 6, 9, 10 and 21-25, include a step of moving a saw blade (or cutting tool) in a particular direction. While Ferrante discloses cutting guides with slots for a saw blade and generally discloses that "cutting instruments (osteotomy saws) are well known in the art" (col. 4, lines 60-61), Ferrante does not explicitly or inherently disclose any method steps of using a saw blade (or cutting tool) to cut a bone by moving the saw blade (or cutting tool) in a particular direction, e.g. relative to a long axis of the saw blade, relative to a particular dimension of the cutting guide surface, and/or relative to the medial and lateral sides of the bone.

Thus, Ferrante does not anticipate each and every method step as recited in the above listed claims as amended.

Therefore, Grounds F(1)(a) - F(1)(o) are **withdrawn**.

Grounds G(1)(a) - G(1)(o): PO arguments of paragraph G, pages 68-69 have been considered. PO argues that the anticipation rejection of claims 1-3, 5-12, 21-25, 28-33 and 42-47 should be withdrawn because Woolson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(G), pages 40-43 have been considered. 3PR argues that Woolson still anticipates the claims as amended.

The examiner agrees with 3PR that Woolson still anticipates the claims as amended, but not necessarily for the reasons argued by 3PR. For example, the examiner does not agree with 3PR's arguments regarding slit 52, e.g. "that only one slit, marked 52 in Figs. 4 and 5, is needed for cutting. There is no teaching in Woolson that the surgeon is required to remove his saw from the one slit (marked 52) and place it into the other slit (unmarked) in order to completely resect the anterior femur." The examiner directs 3PR's attention to Fig. 4, wherein the lead line from character reference number 52 points to the slit on the "left" side of the cutting guide, and then to Fig. 5, wherein the lead line from character reference number 52 points to the slit on the "right" side of the cutting guide (with "left" and "right" being defined as the cutting guide is viewed in Fig. 5). Thus, it is clear that Woolson's reference to "a slit 52" (col. 6, line 24) includes the slit on both sides of the cutting guide, and that the disclosure in

Woodson of "a saw 56 cutting through slit 52 makes an initial anterior femoral cut flush with the anterior femoral cortex" (col. 6, lines 26-28) is referring to making the femoral cut by passing the saw blade through slit 52 on both sides of the guide. However, the examiner sees that "the guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of the cutting-surface defining member 50 as shown in Figs. 4 and 5, i.e. either the "left" L-shaped portion of member 50 or the "right" L-shaped portion of member 50. So defined, Woolson anticipates the above listed claims.

Therefore, Grounds G(1)(a) - G(1)(s) are **sustained**.

New Grounds of Rejection

As an initial matter: In the Notice re Defective Paper in *Inter Partes* Reexamination mailed 3/25/11, PO was required, *inter alia*, to provide an explanation of the support in the disclosure of the patent for the changes to the claims made by the amendment paper. PO's Response filed 4/22/11, on p. 44, included the following:

"Explanation of support: Support for the claim amendments can be found at least at Figure 18 and the accompanying text."

Fig. 18 shows an L-shaped tibial cutting guide having a slot 322 through which a cutting tool may be passed. The brief description of Fig. 18 is as follows:

"FIG. 18 is a perspective view of another alternate embodiment of a partial cutting guide for use in the present invention when the patellar tendon, patella, or quad tendon interferes with placement of the cutting guide about the tibia."

The complete "accompanying text" for Fig. 18 is found in col. 19, line 54 through col. 20, line 8, and reads as follows:

"FIG. 18 shows an embodiment of the cutting guide for use when the patellar tendon, the patella, or the quad tendon interferes with the placement of the other cutting guides of the present invention. As shown in FIG. 18, the cutting guide 350 may be directly interconnected with the alignment rod, and positioned on the tibia as hereinbefore set forth. Basically, this embodiment of the invention includes only one cutting guide. The cutting guide 350 and the cutting guide slot 322 may be wider than the previous embodiments to help stabilize the milling bit in operation. In this embodiment, the milling bit may be plunged across the tibia, and then moved therealong. The milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to tissue about the tibia. Additionally, a support member, not shown, could be provided to extend from the cutting guide 350, over and across the tibia to the other side thereof where it could have a slot to capture the milling bit and provide additional support thereto. The reference numerals 338, 360 and 392 correspond to the reference numerals 238, 260 and 292 respectively."

The above has been included so that the record is clear as to the full content of the '541 patent disclosure with regard to the cutting guide of Fig. 18. What can be gleaned from this section of the patent disclosure includes:

1) Cutting guide 350 is for guiding a cutting tool for cutting the proximal end of the tibia;

2) Cutting guide 350 is L-shaped;

2) Slot 322 is wide enough to accommodate a milling bit.

However, there is no support in the patent disclosure for the following:

1) No disclosure as to the relative lengths of each "leg" of the L-shaped guide 350. Assuming that Fig. 18 shows the right proximal tibia, there is no disclosure as to whether the "leg" shown extending along the lateral side of the tibia is longer or shorter than the "leg" shown extending along the anterior side of the tibia.

4) No disclosure of any additional embodiments, e.g. a "mirror image" L-shaped guide designed for placement along the anterior and medial sides of the tibia;

2) No disclosure of using tibial cutting guide 350 in a method of cutting the femur;

3) No disclosure of any similarly shaped (e.g. L-shaped) cutting guides for use on the femur.

Therefore, since PO amended several claims to include subject matter for which there is no support in the patent disclosure, the following new grounds of rejection under 35 USC 112 are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 13-20, 26, 39, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claim 5 -- no written description of a method for a knee implant procedure having a step of positioning a guide along only one of a medial or lateral side and proximate an end of a long bone, wherein at least one guide surface has a longer dimension generally along the one of the medial or the lateral side.

As to claim 13 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side.

As to claim 16 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only one of the medial side or a lateral side of the knee with no portion of the femoral cut guide positioned along the other of a corresponding compartment of the medial side or the lateral side of the femur.

As to claim 26 -- no written description of a method for providing implants, instrumentation and information for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 6 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 21 -- "compartment" in line 8 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 8 "*corresponding* compartment."

As to claim 23 -- "compartment" in line 13 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 13 "*corresponding* compartment."

3PR's proposed 35 USC 112 rejections of claims 9, 10, 24 and 25 are **not adopted** because the terms "medial aspect" and "lateral aspect" are original claim language and are therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 5 and 22 are **not adopted** because the term "at least a portion" is original claim language and is therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 13 and 26 are **not adopted** because the phrase "positioning the femoral cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee" can be understood by one of ordinary skill in the art. Although the specification lacks any disclosure to an L-shaped guide for cutting the femur (addressed above in the 112/1st paragraph section), assuming such a guide were to exist and it was L-shaped similar to the Fig. 18 tibial cutting guide 350 wherein the length of the anterior side "leg" of the guide was shorter than the width of the anterior side of the femur, one of ordinary skill in the art would understand that such an L-shaped femoral cutting guide could "read on" the above recited claim language.

3PR's proposed 35 USC 112 rejections of claims 35-38 and 49-52 are **not adopted.** These claims were originally dependent claims, and have been rewritten in independent form with no changes in any of the claim language (i.e. all of the underlined "new" text in each rewritten claim is verbatim from each original base claim), and the nature of the rewriting does not raise a new question. Per MPEP 2258(II), "If a dependent claim is rewritten as an independent claim in a reexamination proceeding, that independent claim cannot be examined as to 35 USC 112, unless the nature of the rewriting raises a new question."

Information Disclosure Statements

Per MPEP 2256, where patents, publications, and other such items of information are submitted by a party (patent owner or third party requester) in

compliance with the requirements of the rules, the requisite degree of consideration to be given to such information will normally be limited by the degree to which the party filing the information citation has explained the content and relevance of the information. The initials of the examiner placed adjacent the citations on the form PTO/SB/08A and 08B or its equivalent, without an indication to the contrary in the record, do not signify that the information has been considered by the examiner any further than to the extent noted above. As to patents and printed publications of record in the patent file from earlier examination, it is pointed out that, even the degree of consideration of information from the patent file and its parent files is dependent on the availability of the information. Thus, if references other than U.S. patents and U.S. patent publications were discarded at the time the patent was issued and were not scanned into the Image File Wrapper, then what was said about the references in the patent's record is the full extent of consideration, unless otherwise indicated.

The information disclosure statement filed on 2/25/11 contains citations of Court Proceedings listed on "Substitute for Form 1449/PTO" forms. The cited Court Proceedings do not constitute prior art; consequently, said forms does not appear to be a proper vehicle for notifying the PTO of this information. However, the copies of these Court Proceedings have been received and made of record in the file and are acknowledged as having been filed as Information From Related Litigation as set forth in MPEP 2001.06(c). Further, while items such as declarations and court documents

are evidence, they are not "prior art" as defined in 37 CFR 1.510 and will not be placed on the face of the patent. Thus, the items are lined through.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,344,541 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

This is an ACTION CLOSING PROSECUTION (ACP); see MPEP § 2671.02.

(1) Pursuant to 37 CFR 1.951(a), the patent owner may once file written comments limited to the issues raised in the reexamination proceeding and/or present a proposed amendment to the claims which amendment will be subject to the criteria of 37 CFR 1.116 as to whether it shall be entered and considered. Such comments and/or proposed amendments must be filed within a time period of 30 days or one month (whichever is longer) from the mailing date of this action. Where the patent owner files such comments and/or a proposed amendment, the third party requester may once file comments under 37 CFR 1.951(b) responding to the patent owner's submission within 30 days from the date of service of the patent owner's submission on the third party requester.

(2) If the patent owner does not timely file comments and/or a proposed amendment pursuant to 37 CFR 1.951(a), then the third party requester is precluded from filing comments under 37 CFR 1.951(b).

(3) Appeal **cannot** be taken from this action, since it is not a final Office action.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Inter Partes* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

David O. Reip
Primary Examiner
Central Reexamination Unit
(571) 272-4702

Conferee

Conferee

Substitute for form 1449/PTO				Complete if Known	
				Application Number	95/001,469
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	
(Use as many sheets as necessary)				First Named Inventor	Haines
				Art Unit	3993
				Examiner Name	David Owen Reip
Sheet	1	of	16	Attorney Docket Number	3293.23USREX1

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
DR		US-3,943,934	03-16-1976	Bent
		US-3,977,289	08-31-1976	Tuke
		US-4,703,751	11-03-1987	Pohl
		US-4,731,086	03-15-1988	Whiteside
		US-4,736,086	04-05-1988	Obara
		US-4,893,619	01-16-1990	Dale
		US-4,926,847	05-22-1990	Luckman
		US-4,935,023	06-19-1990	Whiteside
		US-4,979,949	12-25-1990	Matsen
		US-5,178,626	01-12-1993	Pappas
		US-5,197,944	03-30-1993	Steele
		US-5,282,803	02-01-1994	Lackey
		US-5,415,663	05-16-1995	Luckman
		US-5,613,969	03-25-1997	Jenkins
		US-5,908,424	06-01-1999	Bertin

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EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
DR		WO 96/24295	08-15-1996	Jenkins	
		EP 0337901	10-18-1989	Broc	x-abstract
		WO 93/22990	11-25-1993	Abrektsson	
		EP 0380451 A2	01-08-1990	Ghisellini	
		EP 0415837 A2	03-06-1991	Douchet	x-abstract
		FR 2635675	03-02-1990	Laboureau	x-abstract
		SE 382155	01-19-1976	Norrbom	x-abstract
		WO 93/25157	12-23-1993	Rau	
		GB2007980	07-21-1982	Harris W H	
		EP 0682916 A2	11-22-1995	Burton	

EXAMINER SIGNATURE	David O. Reip	DATE CONSIDERED	8/16/11

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

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DR		US-3,906,550	09-23-1975	Rostoker
		US-4,069,824	01-24-1978	Weinstock
		US-4,479,271	10-30-1984	Bolesky
		US-4,584,999	04-29-1986	Arnegger
		US-4,659,331	04-21-1987	Matthews
		US-4,693,721	09-15-1987	Ducheyne
		US-4,709,699	12-01-1987	Michael
		US-4,718,413	01-12-1988	Johnson
		US-5,032,134	07-161991	Lindwer
		US-5,092,869	03-03-1992	Warsaw
		US-5,176,710	01-05-1993	Hahn
		US-5,275,603	01-04-1994	Ferrante
		US-5,405,349	04-11-1995	Burkinshaw
		US-5,417,694	05-23-1995	Marik
		US-5,417,695	05-23-1995	Axelson

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DR		JP 02-501806A	01-29-1983	Johnson	x-abstract
		EP 0104732	04-04-1984	Cooke	
		JP 05-277130	10-26-1993	Ferrante	x-abstract
		JP 01-119244	05-01-1989	Yasui	x-abstract
		JP 01-126957	05-19-1989	Thimsen	x-abstract
		JP 01-209055	08-22-1989	Sapega	x-abstract
		JP 02-057247	02-07-1990	Jellicoe	x-abstract
		JP 02-234756	09-17-1990	Alexon	x-abstract
		JP 02-234757	09-17-1990	Whiteside	x-abstract
		JP 02-239861	09-21-1990	Whiteside	x-abstract

EXAMINER SIGNATURE	David Owen Reip	DATE CONSIDERED	8/16/11

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DR		US-5,122,144	06-16-1992	Bert
		US-5,190,547	03-02-1993	Barber Jr.
		US-5,206,023	04-27-1993	Hunziker
		US-5,236,875	08-17-1993	Trigg
		US-5,358,529	10-25-1994	Davidson
		US-5,364,402	11-15-1994	Mumme
		US-5,470,335	11-28-1995	Du Toit
		US-5,520,695	05-28-1996	Luckman
		US-5,571,100	11-05-1996	Goble
		US-5,769,855	06-23-1998	Bertin
		US-5,769,899	06-23-1998	Schwartz
		US-6,236,875	05-22-2001	Becholz
		US-6,482,409	11-19-2002	Lobb
		US-7,077,867	07-18-2006	Pope

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DR		JP 02-243143	09-27-1990	Zarnowski	x-abstract
		JP 02-246971	10-02-1990	Luckman	x-abstract
		JP 03-032663	02-13-1991	Matsui	x-abstract
		JP 04-297254	10-21-1992	Coates	x-abstract
		JP 04-361746	12-15-1992	Inoue	x-abstract
		WO 1991/00061	01-10-1991	Baumgart	x-abstract
		JP 05-502814	05-20-1993	Quadri	x-abstract
		WO 91/10408	07-25-1991	Caspari	
		WO 81/03122	11-12-1981	Burke	
		JP/2002/274214	11-08-1990	Arimoto Tadahiro	x-abstract

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DR		US-3,953,899	05-04-1976	Charnley
		US-3,953,899	05-04-1976	Chamely
		US-4,340,978	07-27-1982	Buechel
		US-4,731,086	03-15-1988	Whiteside
		US-4,736,086	04-05-1998	Obara
		US-4,759,350	07-26-1988	Dunn
		US-4,880,429	11-14-1989	Stone
		US-4,919,667	04-24-1990	Richmond
		US-4,971,075	11-20-1990	Lee
		US-5,002,547	03-26-1991	Poggie
		US-5,007,934	04-16-1991	Stone
		US-5,041,138	08-20-1991	Vacanti
		US-5,112,336	05-12-1992	Krevolin
		US-5,462,551	10-31-1995	Bailey

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
DR		JP 58-209343	12-06-1983	Mains	x-abstract
		JP 61-170453	08-01-1986	Walker	x-abstract
		JP 62-133948	06-17-1987	Kaufman	x-abstract
		JP 62-254750	06-11-1987	Russell	x-abstract
		JP 05-269140	10-19-1993	Dietz	x-abstract
		JP 06-233775	08-23-1994	Mn Mining	x-abstract
		JP 05-03880	01-14-1993	Nishijima	x-abstract
		JP 06-08033	01-18-1994	Dietz	x-abstract
		JP 06-38971	02-15-1994	Johnson	x-abstract
		JP 06-237941	08-30-1994	Ashby	x-abstract

EXAMINER SIGNATURE	David O. Reip	DATE CONSIDERED	8/16/11

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DR		US-5,824, 105	10-20-1998	Ries
		US-3,748,662	07-31-1973	Helfet
		US-3,958,278	05-25-1976	Lee
		US-4,016,606	04-12-1977	Murray
		US-4,207,627	06-17-1980	Cloutier
		US-5,370,699	12-06-1994	Hood
		US-5,540,695	07-30-1996	Levy
		US-5,643,402	07-01-1997	Mumme
		US-5,649,928	07-22-1997	Grundei
		US-5,690,635	11-25-1997	Matsen, III
✓		US-5,690,637	11-25-1997	Wen

FOREIGN PATENT DOCUMENTS

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DR		EP 0555003	08-11-1993	Ashby	
		EP 556998	08-25-1993	Ferrante	
		WO 94/05212	03-17-1994	McNulty	
		WO 94/14366	07-07-1994	Fisher	
		WO 94/08528	04-28-1994	Ferrante	
		EP 0327249 A2	08-09-1989	Poggie	
		EP 0243109 B1	10-28-1987	Russell	
		EP 0121142	10-10-1984	Whiteside	
		WO 94/09730	05-11-1994	Steele	
		JP 5-41510	06-08-1993		x-abstract
		JP 6-217984	08-09-1994	Hempel	x-abstract
		JP 7-136200	05-30-1995	Bertin	x-abstract
		JP 7-501966	03-02-1995		x-abstract
✓		JP 7-116185	05-09-1995	Axelson Jr.	x-abstract

EXAMINER SIGNATURE	David O. Reip	DATE CONSIDERED	8/16/11

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DR		US-4,963,152	10-16-1990	Hofmann
		US-5,007,933	04-16-1991	Sidebotham
		US-5,021,061	06-04-1991	Wevers
		US-5,062,852	11-05-1991	Dorr
		US-5,080,675	01-14-1992	Lawes
		US-5,116,375	05-26-1992	Hofmann
		US-5,133,758	07-28-1992	Hollister
		US-5,133,759	07-28-1992	Turner
		US-5,147,405	09-15-1992	Van Zile
		US-5,201,881	04-13-1993	Evans
		US-5,203,807	04-20-1993	Evans
		US-5,219,362	06-15-1993	Tuke
		US-5,236,461	08-17-1993	Forte
		US-5,282,867	02-01-1994	Mikhall
		US-5,326,358	07-05-1994	Aubriot
		US-5,330,533	07-19-1994	Walker
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DR		GB 2296443	07-03-1996	Peyrou	
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EXAMINER SIGNATURE	David O. Reip	DATE CONSIDERED	8/16/11

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	95/001,469
				Filing Date	
				First Named Inventor	Haines
				Art Unit	3993
				Examiner Name	David Owen Reip
Sheet	7	of	16	Attorney Docket Number	3293.23USREX1

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		US-4,249,270	02-10-1981	Bahler
		US-4,711,639	12-08-1987	Grundel
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DR		FR 2701387	08-19-1994	Reach	x-abstract
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				Examiner Name	David Owen Reip
Sheet	9	of	16	Attorney Docket Number	3293.23USREX1

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				First Named Inventor	Haines
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				Examiner Name	David Owen Reip
Sheet	10	of	16	Attorney Docket Number	3293.23USREX1

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		Application and File History of U.S. Patent Application Serial No. 12/757,778,	

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Sheet	14	of	16	Attorney Docket Number	3293.23USREX1

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EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
DR		Whiteside Ortholoc Total Knee System, Dow Coming Wright, pages ZH000109679-ZH000109690.	
		ZIMMER, InsalllBumstein II, Modular Knee System, Surgical Technique, pages ZH000109691-ZH000109710	
		Documents labeled ZHGOOOI57188- ZHG000157198 disclosed in HSO, Inc. v. Zimmer et al., 11 pages.	
		Documents labeled ZHGOOOI57226- ZHG000157253 disclosed in HSO, Inc. v. Zimmer et al, 28 pages	
		Documents labeled ZHGOOOI57254- ZHG000157270 disclosed in HSO, Inc. v. Zimmer et al., 17 pages	
		Case 1:08-cv-01566, Document No. 83-3, Exhibit 1, *Anatomical Terms*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-4, Exhibit 2, *Spatial Terms*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-5, Exhibit 3, *Healthy vs. Arthritic Knee*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-6, Exhibit 4, *Post TKA Knee Joint*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-7, Exhibit 5, *Knee Implants*, Filed November 17, 2008, 2 pages.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	95/001,469
				Filing Date	
				First Named Inventor	Haines
				Art Unit	3993
				Examiner Name	David Owen Reip
Sheet	15	of	16	Attorney Docket Number	3293.23USREX1

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DR		Case 1:08-cv-01566, Document No. 83-8, Exhibit 6, *Traditional vs. Minimally Invasive*, November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-9, Exhibit 7, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-10, Exhibit 8, *Total Knee Replacement*, Filed November 17, 2008, © 2000, Swarm Interactive, www.swarminteractive.com, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-13, Exhibit 11, *Deferred Prosecution Agreement*, Filed November 17, 2008, 26 pages.	
		Case 1:08-cv-01566, Document No. 83-18, Exhibit 16, Part 1, *Zimmer Computer Assisted Solutions Electromagnetic Quad-Spring, Surgical Technique*, Filed November 17, 2008, 3 pages.	
		Case 1:08-cv-01566, Document No. 83-19, Exhibit 16, Part 2, *Zimmer Computer Assisted Solutions Electromagnetic Quad-Spring, Surgical Technique*, Filed November 17, 2008, 4 pages.	
		Case 1:08-cv-01566, Document No. 83-20, Exhibit 16, Part 3, *Zimmer Computer Assisted Solutions Electromagnetic Quad-Spring, Surgical Technique*, Filed November 17, 2008, 4 pages.	
		Case 1:08-cv-01566, Document No. 83-23, Exhibit 19, *Haines Family Tree for '541 Patent*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-25, Exhibit 21, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-29, Exhibit 25, *Webster's Ninth New Collegiate Dictionary (includes page 905)*, Filed November 17, 2008, © 1985, 5 pages.	
		Case 1:08-cv-01566, Document No. 83-30, Exhibit 26, *Figure 18 of Patent No. 7,334,541*, Filed November 17, 2008, 2 pages.	
✓		Case 1:08-cv-01566, Document No. 83-31, Exhibit 27, *Langenscheidt Merriam-Webster Medical Dictionary*, Filed November 17, 2008, © 2006, 6 pages.	

EXAMINER SIGNATURE	David O. Reip	DATE CONSIDERED	8/16/11

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Sheet	16	of	16	Attorney Docket Number	3293.23USREX1

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DR		Case 1:08-cv-01566, Document No. 83-33, Exhibit 29, *Claim 21 of U.S. Patent No. 7,334,541*, Filed November 17, 2008, 2 pages.	
		Case 1:08-cv-01566, Document No. 83-34, Exhibit 30, *Webster's Ninth New Collegiate Dictionary (includes pages 56 & 73 of the dictionary)*, Filed November 17, 2008, © 1985, 6 pages.	
		Case 1:08-cv-01566, Document No. 83-35, Exhibit 31, *Mosby's Medical Dictionary 7th Edition*, Filed November 17, 2008, © 2006, 6 pages.	
		Case 1:08-cv-01566, Document No. 83-2, Hudson Surgical Design, Inc. vs. Zimmer Holdings, Inc.; Zimmer, Inc.; Rush System for Health; and Rush University Medical Center, *Index of Exhibits (Exhibit Nos. 1-31) to Hudson Surgical Design, Inc.'s Opening Brief on Claim Construction,* Filed November 17, 2008, 2 pages.	

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DR		~~HUDSON SURGICAL DESIGN, INC. V. BIOMET, INC., *Complaint*, Case: 1:10-cv-04459, Document 1 (includes Document 1, 1-1 and 1-2), Filed July 19, 2010, 74 pages.~~	
		~~HUDSON SURGICAL DESIGN, INC. V. BIOMET, INC., *Answer, Affirmative Defenses, and Counterclaim of Biomet, Inc.*, Case: 1:10-cv-04459, Document 14, Filed August 31, 2010, PageID # 89-104.~~	
		~~HUDSON SURGICAL DESIGN, INC. V. BIOMET ORTHOPEDICS, LLC and BIOMET MANUFACTURING CORPORATION, *Answer, Affirmative Defenses, and Counterclaim of Biomet Orthopedics, LLC and Biomet Manufacturing Corporation to the First Amended Complaint*, Case: 1:10-cv-04459, Document 19, Filed September 28, 2010 PageID# 194-207.~~	
		~~HUDSON SURGICAL DESIGN, INC. V. BIOMET ORTHOPEDICS, LLC and BIOMET MANUFACTURING CORPORATION, *Hudson Surgical Design Inc.'s Answer to Counterclaims of Biomet Orthopedics, LLC and Biomet Manufacturing Corporation*, Case: 1:10-cv-04459, Document 27, Filed October 11, 2010, PageID# 245-249.~~	
		~~HUDSON SURGICAL DESIGN, INC. V. BIOMET ORTHOPEDICS, LLC and BIOMET MANUFACTURING CORPORATION, *First Amended Complaint*, Case: 1:10-cv-04459, Document 17, Filed September 14, 2010, PageID# 108-183.~~	

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DR		~~Case 1:08-cv-01566, Hudson Surgical Design, Inc. vs. Zimmer Holdings, Inc.; Zimmer, Inc.; Rush System for Health; and Rush University Medical Center, *Hudson Surgical Design, Inc.'s October 20, 2008, Supplemental Answers to Defendant Rush University Medical Center's First Set of Interrogatories*, dated October 20, 2008, 23 pages.~~	
		~~Case 1:08-cv-01566, Hudson Surgical Design, Inc. vs. Zimmer Holdings, Inc.; Zimmer, Inc.; Rush System for Health; and Rush University Medical Center, *Hudson Surgical Design, Inc.'s October 20, 2008, Supplemental Answers to Zimmer, Inc.'s First Set of Interrogatories*,~~ Filed dated October 20, 2008, ~~21~~ pages.	
		~~Case 1:08-cv-01566, Hudson Surgical Design, Inc. vs. Zimmer Holdings, Inc.; Zimmer, Inc.; Rush System for Health; and Rush University Medical Center, *Joint Claim Construction Chart*, Filed dated October 24, 2008, 14 pages.~~	
		~~Case 1:08-cv-01566, Hudson Surgical Design, Inc. vs. Zimmer Holdings, Inc.; Zimmer, Inc.; Rush System for Health; and Rush University Medical Center, *Joint Claim Construction Chart* Filed dated October 24, 2008, 14 pages.~~	
		~~Hudson Surgical Design, Inc. vs. Depuy Orthopaedics, Inc., Defendant Depuy Orthopaedics, Inc.'s Local Patent Rule 2.3 Initial Non-Infringement, Invalidity, and Unenforceability Contentions, Civil Action No. 10-CV-02103, Dated September 27, 2010, 13 pages.~~	
		~~Hudson Surgical Design v. Zimmer Holdings, Inc., et al., Zimmer, Inc.'s and Zimmer Holding Inc's Supplemental Responses to Hudson Surgical Design, Inc.'s First Set of Interrogatories (Nos. 1-18) To Each of Them, dated August 1, 2008.~~	
V		~~Hudson Surgical Design v. Zimmer Holdings, Inc., et al., Revised Final Claim Construction Chart, dated March 11, 2009.~~	

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DR		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer Inc., Rush System for Health and Rush University Medical Center, Hudson Surgical Design, Inc.'s Opening Brief On Claim Construction Case No.: 1:08-cv-01566, Civil Action No. 08C1566, Document No. 83, Filed November 17, 2008, pages 1-40 (also includes Exhibits 1-40).~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer, Inc. Rush System For Health and Rush University Medical Center, Civil Action No. 08-cv-01566, Statement of Thomas D. Petersen, MD. (including Exhibit A-G), Dated September 2, 2009~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc. et al.*, Notification of Docket Entry, Filed September 21,2009, Document 138, Case No.1:08-cv-01566, 1 page.~~	
		~~*Hudson Surgical Design, Inc. v Zimmer Holdings, Inc., et. al*, Case No. 1:08-cv-01566, January 27, 2009, Volume I-A, Transcript of Markman Hearing Before the Honorable Virginia M. Kendal United States District Judge, pages 1-66 & index pages 1-12.~~	
		~~*Hudson Surgical Design, Inc. v Zimmer Holdings, Inc., et. al*, Case No. 1:08-cv-01566, January 27,2009, Volume I-B, Transcript of Markman Hearing Before the Honorable Virginia M. Kendal United States District Judge, pages 67-133, & index pages 1-13.~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer, Inc., Rush System for Health and Rush University Medical Center, Hudson Surgical Design, Inc.'s Reply Brief on Claim Construction, Civil Action No. 08-cv-01566 Document No. 97, Filed December 19,2008, pages 1-28.~~	

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DR		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer, Inc., Rush System for Health and Rush University Medical Center, Rush System for Health's and Rush University Medical Center' Answer to First Amended Complaint, Filed May 9, 2008, Case No. 08-cv-01566, pages 1-7.~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer, Inc., Rush System for Health and Rush University Medical Center. Plaintiffs Reply to Counterclaims of Defendants Zimmer Holdings, Inc. and Zimmer, Inc., Case No. 08-cv-01566, Filed May 19,2008 pages 1-5.~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer Inc. Rush System for Health and Rush University Medical Center, Civil Action No. 08-cv-01566, Statement of Dr. E Marlowe Goble (including Non-Confidential Exhibits)~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer Inc., Rush System for Health and Rush University Medical Center, Defendant's Responsive Claim Construction Brief, Case No.: 1 :08-cv-01566, Document No. 95, Filed December 8, 2008, pages 1-40 (also included is Exhibit 1-8).~~	
		~~Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc., Zimmer, Inc., Rush System for Health and Rush University Medical Center. First Amended Complaint, Filed April 11, 2008, Case: 08-cv-01566, pages 1-8.~~	
		~~*Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, Zimmer, Inc., Rush System for Health and Rush University Medical Center. Answer, Affirmative Defenses and Counterclaims of Zimmer Holdings, Inc. and Zimmer, Inc. Filed May 9,2008, Case No. 08-cv-01566, pages 1-10.~~	

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		~~Notice of Allowance and Fees Due; USPTO App. No.: 10/977,365, 5 pages~~ PRIOR ART NOT A PATENT OR PRINTED PUBLICATION	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,469	10/15/2010	7344541	BIOMET1	7743

7590 05/21/2012

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REIP, DAVID OWEN	
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The time period for reply, if any, is set in the attached communication.

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Transmittal of Communication to Third Party Requester *Inter Partes* Reexamination

REEXAMINATION CONTROL NUMBER *95/001,469*.

PATENT NUMBER *7,344,541*.

TECHNOLOGY CENTER *3999*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

Right of Appeal Notice (37 CFR 1.953)	**Control No.**	**Patent Under Reexamination**
	95/001,469	7344541
	Examiner	**Art Unit**
	DAVID O. REIP	3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:
Patent Owner on 29 September, 2011
Third Party(ies) on 10/31/11

Patent owner and/or third party requester(s) may file a notice of appeal with respect to any adverse decision with payment of the fee set forth in 37 CFR 41.20(b)(1) within **one-month or thirty-days (whichever is longer)**. See MPEP 2671. In addition, a party may file a notice of **cross** appeal and pay the 37 CFR 41.20(b)(1) fee **within fourteen days of service** of an opposing party's timely filed notice of appeal. See MPEP 2672.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

If no party timely files a notice of appeal, prosecution on the merits of this reexamination proceeding will be concluded, and the Director of the USPTO will proceed to issue and publish a certificate under 37 CFR 1.997 in accordance with this Office action.

The proposed amendment filed 29 September, 2011 ☐ will be entered ☒ will not be entered*

*Reasons for non-entry are given in the body of this notice.

1a. ☒ Claims 1-54 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are confirmed. [Unamended patent claims].
4. ☐ Claims _____ are patentable. [Amended or new claims].
5. ☒ Claims 1-54 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The drawings filed on _____ ☐ are acceptable. ☐ are not acceptable.
8. ☐ The drawing correction request filed on _____ is ☐ approved. ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d) or (f). The certified copy has:
   ☐ been received. ☐ not been received. ☐ been filed in Application/Control No. _____.
10. ☐ Other _____

Attachments

1. ☐ Notice of References Cited by Examiner, PTO-892
2. ☐ Information Disclosure Citation, PTO/SB/08
3. ☐ _____

Inter Partes Reexamination

Background

On 10/15/10, the request for *Inter Partes* reexamination of U.S. Pat. No. 7,344,541 was filed by the third party requester ("3PR").

On 11/10/10, the Decision granting reexamination was mailed.

On 11/23/10, a non-final Office action was mailed. All 54 patent claims were rejected on various grounds, as proposed by 3PR and adopted by the examiner.

On 1/24/11, patent owner ("PO") filed a timely response which included claim amendments. It was noted that the amendment did not comply with 37 CFR 1.530 and was therefore not entered.

On 2/23/11, 3PR filed Comments in response to PO's 1/24/11 response and amendment.

On 3/25/11, a Notice re Defective Paper in *Inter Partes* Reexamination was mailed wherein the defects in PO's 1/24/11 response and amendment were noted. PO was given 30-days or one month (whichever was longer) to file a corrected response and amendment.

0n 4/22/11, PO filed a timely Response to Notice of Defective Paper. It is noted that PO's response included only a page 1 Transmittal notice, pages 2-43 of corrected claim amendments, and a page 44 "Status of claims and support for claim changes." PO did not resubmit their Remarks section. Therefore, the examiner has assumed PO's remarks are the same as those on pages 48-73 of PO's 1/24/11 response. With that

assumption, it is then noted that PO's complete response includes pages that are numbered 1-44 and 48-73, and that there are no pages numbered 45-47.

On 5/23/11, 3PR filed Comments in response to PO's response to Notice re Defective Paper.

On 8/29/11, an Action Closing Prosecution was mailed.

On 9/29/11, PO timely filed a substantive amendment and comments under 37 CFR 1.951(a).

On 10/31/11, 3PR filed Comments under 37 CFR 1.951(b).

PO Comments/Amendments and 3PR Comments after ACP

PO's 9/29/11 proposed Comments/Amendments paper is defective and is **not entered**, for at least the following reasons:

(1) Substantially all amended claims are mismarked. 37 CFR 1.530 specifies how patent claims are to be marked when amended during reexamination, e.g. matter to be omitted by the reexamination proceeding must be enclosed in brackets, and matter to be added by the reexamination proceeding must be underlined (§ 1.530(f)), and all amendments must be made relative to the patent specification, including the claims, and drawings, which are in effect as of the date of filing the request for reexamination (§ 1.530(i)). In the 9/29/11 proposed amendment, PO failed to continue with the underlining of claim text added in the 4/22/11 amendment, and altogether deleted claim text that had been enclosed in brackets in the 4/22/11 amendment.

(2) The substance of several of the proposed amendments to the claims extends beyond compliance with "any requirement of form expressly set forth in a previous Office action" per 37 CFR 1.116(1). Further, the proposed amendments themselves raise new issues under 35 USC 112. For example, claims 1, 6, 21 and 23 were rejected under 35 USC 112, 2nd paragraph as being indefinite for failing to provide antecedent basis for the term "compartment." In response, the PO proposed a substantive amendment to each of claims 1, 6, 21 and 23 by adding, *inter alia*, "the long bone of the knee joint defining a medial compartment including the medial side, a lateral compartment including the lateral side, and a central compartment between the medial compartment and the lateral compartment." There are several deficiencies with respect to said proposed amendment. First, there is no support in the '541 patent specification for the phrases "medial compartment," "lateral compartment," and "central compartment." The term "compartment" appears only in original patent claims 39, 40, 53 and 54, associated with the term "contralateral," i.e. "a contralateral compartment." Additionally, the term "central" appears in the specification as follows:

1) Col.1, line 54, "the central axis of the femur"

2) Col. 13, line 16, "a central aperture 86"

3) Col. 17, lines 49-50, 52 and 53, "central cutting portion 257"

4) Col. 19, lines 5-6, "central cutting portion 257"

5) Col. 26, line 51, "a central notch"

6) Col. 31, line 1, "a central bore 878"

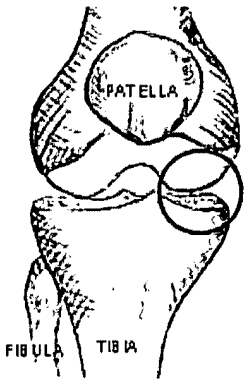
7) Col. 34, line 23, "a central notch"

Thus, while the term "central" appears in the specification in the above instances, the term is not associated with the phrase "central compartment," nor are any of the instances where "central" appears in the specification associated with defining a compartment that is located "between the medial compartment and the lateral compartment."

Further, the literature suggests that, when discussing the anatomy of the knee with regard to knee arthritis, doctors describe three "compartments" in the knee.

From http://www.kneeguru.co.uk/KNEEnotes/node/1851 website:

"These are not actual discrete pockets, but are three areas where the bones of the knee make contact with one another. Two of the compartments are formed by the rounded ends of the femur (condyles) where they make contact with the flat top of the tibia bone. These are the medial and lateral compartment. The third compartment is where the patella (kneecap) makes contact with the femur bone below it. This is the patellofemoral compartment."

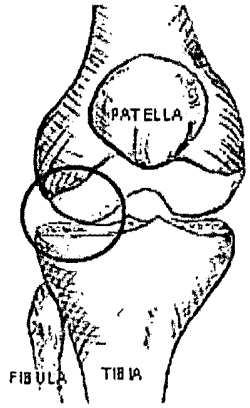


THE MEDIAL COMPARTMENT

The inner joint surfaces of the long bones, femur (thighbone) and tibia (shinbone) and the meniscus (shock absorber) wedged between them.

Medial compartment osteoarthritis (OA) is more frequent than lateral compartment OA and commonly follows damage to the meniscus ('knee cartilages'), the medial meniscus being more vulnerable to injury than the lateral meniscus.

Remove the whole meniscus on the medial side ('total meniscectomy') and the altered forces will eventually result in medial compartment OA, the joint space on that side will collapse, the bone will try to heal things by pushing out bridges of bone, further distorting the anatomy, the cartilage will become under stress and eventually break down. Bow-legs may result.

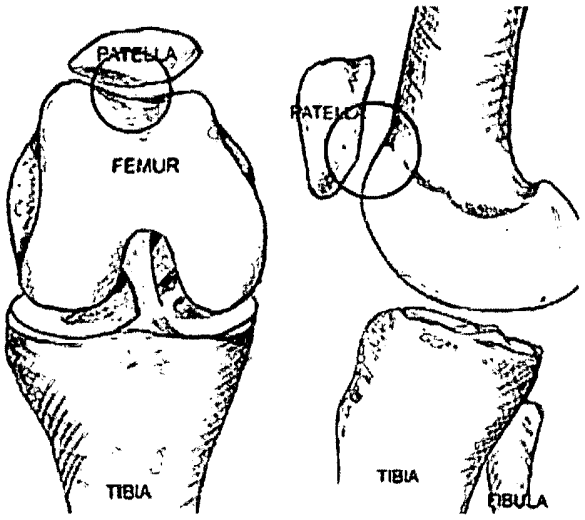


THE LATERAL COMPARTMENT

The same on the outer side (remember, the fibula bone is on the outer lateral side).

The same thing may happen on the lateral side, but this is less common due to biomechanical factors in the menisci. Take out the whole meniscus on the lateral (outer) side and eventually lateral compartment osteoarthritis will develop, with the leg will become knock-kneed - the opposite of medial compartment OA.

OA of medial or lateral compartment may also follow an injury, where a chondral defect may have occurred - a chunk of joint surface knocked off into the joint, leaving a crater in the joint surface and a 'loose body' in the joint cavity. Or untreated cruciate ligament damage may cause joint instability and joint surface and meniscal damage - leading to OA.



THE PATELLO-FEMORAL COMPARTMENT

The patellofemoral compartment - the joint between the undersurface of the kneecap (patella) and the femur.

Patellofemoral compartment OA usually follows problems with the alignment of the kneecap onto the underlying thighbone (femur). Joint surface damage can occur at the side where there is increased contact (too much pressure) and also at the side where there is decreased pressure (too little contact).

In summary, one of ordinary skill in the art would understand that the *interface* between the femur and tibia at the knee joint define the "medial compartment" and the "lateral compartment," and the *interface* between the femur and patella defines the "patellofemoral" compartment. However, since a "central compartment" is not recognized in the literature, one of ordinary skill in the art would not interpret a claim recitation to "a central compartment" as being a compartment that is located "between the medial compartment and the lateral compartment," nor would one of ordinary skill in the art equate "a central compartment" with the patellofemoral compartment.

(3) MPEP 2673(III) instructs, "When a proposed amendment is not entered, the examiner will provide a detailed explanation of the reasons for not entering the proposed amendment. For example, if the claims as amended would present a new issue requiring further consideration or search, the new issue should be identified, and an explanation provided as to why a new search is necessary and/or why more than nominal consideration is necessary." As discussed above in (2), the potential new 35 USC 112 issues raised as a result of the proposed amendment would clearly require more than nominal consideration.

(4) On p. 52 of PO's comments, PO argues "that even if the proposed amendment is not entered, the arguments presented below are equally applicable to the claims as interpreted in view of the specification and file history." However, in many instances, PO's arguments are either based exclusively upon claim language first

introduced in the instant proposed amendment, or have so intertwined arguments as to prosecution history with arguments as to the instant proposed amendment that the two lines of argument are not readily separable.

For example, with respect to the Biomet reference and the Grounds B(1) anticipation rejection, PO argues (on pgs. 59-60) that, "The ACP adopts the arguments of the Requester that only a portion of one of the guides of the Biomet Brochure can be used to anticipate the claims. However, as noted previously, such a construction of the pending claims is inherently improper in view of the specification and file history and is expressly precluded by the proposed amendment submitted herewith. In view of the proper scope of the pending claims and/or the proposed amendment, the Biomet Brochure does not anticipate the amended claims because..."

In a further example, with respect to the Protek F/S Modular reference and the Grounds D(1) anticipation rejection, PO argues (on p. 66) that, "As noted previously, in view of the pending claims having overcome the Bert reference in prosecution and in view of the proposed amendments submitted herewith, the claims cannot be anticipated..."

Thus, since PO's Comments portion of the 9/29/11 Comments/Amendments paper is not severable from the proposed Amendments portion, and the proposed amendments are, *inter alia*, defective as discussed in above in (1), the whole of PO's 9/29/11 response is not entered.

Therefore, for at least the above reasons, PO's 9/29/11 Comments/Amendments paper after ACP is **not entered**.

Given PO's 9/29/11 paper is not entered, 3PR's Comments paper filed 10/31/11 is correspondingly **not entered**. Of further note -- even if PO's 9/29/11 paper had been entered, 3PR's 10/31/11 Comments would not have been entered because said Comments exceed the 50 pages in length limit set forth in 37 CFR 1.943(b). Specifically, 3PR's "main" Comments paper exceeds the 50-page limit (by six pages) because the Table of Contents pages i-v and the List of Exhibits page iv are included in the page count – these pages do not fall within the "amendments, appendices, and reference materials" exclusion. Additionally, submission of claim charts comparing claim limitations with references are also included in the page count...they are not excluded as "appendices of claims" per 37 CFR 1.943(b). Therefore, since the additional 421 pages constituting Exhibit B (34 pages), Exhibit C (200 pages) and Exhibit D (187 pages) are included in the page count, 3PR's 10/31/11 Comments paper exceeds the 50-page limit by 427 pages.

MPEP 2673(II) instructs, "Where a submission has been filed under 37 CFR 1.951(a) (or 37 CFR 1.951(b))) and that submission is incomplete or is defective, the examiner should notify the parties, in the RAN, that the submission has not been considered, and that no additional opportunity is available to correct the defect(s) in the

submission, because 37 CFR 1.951(a) and (b) provide that comments may only be filed "once." ***The parties are so notified.***

Since neither party has filed enterable responses after ACP, prosecution advances to the Right of Appeal Notice (RAN). The remainder of the instant RAN is substantially the same action and arguments as presented in the ACP mailed 8/29/11.

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Previous Prosecution

In the request, 3PR proposed the following grounds of rejection (see 3PR's Table of Contents, pages iv-xi):

Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson.

Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular.

Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen.

Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102 as being anticipated by Biomet Brochure.

Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II.

Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular.

Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen.

Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferrante.

Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson.

In the non-final Office action mailed 11/23/10, the examiner adopted all proposed rejections except the following:

As to Grounds A(1)(a) - A (1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds A(2)(a) - A(2)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds B(1)(a) - B(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds D(1)(a) - D(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds F(1)(a) - F(1)(o): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds G(1)(a) - G(1)(o): The proposed rejections of claims 4, 27, 34, 41 and 48 were not adopted.

PO's Amendment, 3PR's Response, and Examiner's decision

Grounds A(1)(a) - A(1)(s): PO arguments of paragraph A, pages 53-56 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Samuelson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(A), pages 13-20 have been considered. 3PR argues that Samuelson still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(A), pages 13-20 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Samuelson, e.g. as depicted in 3PR's Fig. 11A mark-up on p.15 of their Comments, wherein swing arm 334 along with arm support 352 defines "the guide surface." Thus, said "the guide surface," when placed in the operative position, would be generally along the medial or lateral side of the long bone being cut *with no other portion of the guide surface positioned along the corresponding compartment of the other of the medial side or the lateral side of the long bone*, as recited in e.g. amended claim 1.

Therefore, Grounds A(1)(a) - A(1)(s) are **sustained**.

Grounds A(2)(a) - A(2)(s) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para.

IV(A), pages 43-45 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds A(3)(a) - A(3)(o) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para. IV(B), pages 45-46 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds B(1)(a) - B(1)(s): PO arguments of paragraph B, pages 56-59 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Biomet Brochure does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(B), pages 20-25 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(B), pages 20-25 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Biomet Brochure, e.g. as depicted in 3PR's drawings on p.22 of their Comments. Additionally, as argued by 3PR, Biomet Brochure at 18 expressly discloses placing only the medial cutting guide arm into the operative position because of the position of the patellar tendon.

Therefore, Grounds B(1)(a) - B(1)(s) are **sustained**.

Grounds C(1)(a) - C(1)(e): PO arguments of paragraph C, pages 59-61 have been considered. PO argues that the anticipation rejection of claims 1-5, 8, 21 and 22 should be withdrawn because Mark II does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(C), pages 25-28 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(C), pages 25-28 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the anterior view drawing at step 5 of the Proximal Tibia Osteotomy shows that with both cutting guide arms retracted, a portion of each arm is positioned along less than one-half a width of the anterior side. Also, as shown at step 7, the medial cutting guide arm is wrapped around the medial tibia and the tibia is saw cut in at least two directions -- 1) anterior to posterior, substantially perpendicular to a longitudinal axis of the anterior cutting guide; and 2) medial to lateral, substantially perpendicular to the curved axis of the medial cutting guide arm.

Therefore, Grounds C(1)(a) - C(1)(e) are **sustained**.

Grounds D(1)(a) - D(1)(s): PO arguments of paragraph D, pages 61-64 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Protek F/S Modular does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(D), pages 28-33 have been considered. 3PR argues that Protek F/S Modular still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(D), pages 28-33 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the Step 2: Resection of the Proximal Tibia on p. 18 of 57 expressly discloses wrapping only the medial cutting guide arm around the medial tibia because the position of the patellar tendon precludes the use of the cutting guide arm on the lateral side. Thus, for example with respect to claim 1, Protek F/S Modular shows "at least a portion of the at least one guide surface is positioned along only one of a medial side or a lateral side and proximate an end of a long bone of a knee joint with no other portion of the guide surface positioned along a corresponding compartment of the other of the medial side or the lateral side of the long bone" as recited.

Therefore, Grounds D(1)(a) - D(1)(s) are **sustained**.

Grounds E(1)(a) - E(1)(o): PO arguments of paragraph E, pages 64-66 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 28-33 and 42-47 should be withdrawn because Matsen does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(E), pages 34-37 have been considered. 3PR argues that Matsen still anticipates the claims as amended.

The examiner agrees with PO. While the Matsen guide as shown in Figs. 19-21 *could* be placed to cover the medial or lateral side of the bone and only a portion of the

anterior side as argued by 3PR, no explicit disclosure of such placement is made in Matsen. Thus, Matsen does not *anticipate* (i.e. expressly or inherently disclose) each and every method step as recited in the above listed claims as amended.

Therefore, Grounds E(1)(a) - E(1)(o) are **withdrawn**.

Grounds F(1)(a) - F(1)(o): PO arguments of paragraph F, pages 66-68 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 27-29, 31-34, 41-43 and 45-48 should be withdrawn because Ferrante does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(F), pages 38-40 have been considered. 3PR argues that Ferrante still anticipates the claims as amended.

The examiner agrees with PO, but not necessarily for the reasons as argued by PO. Upon reconsideration, the examiner notes that each independent claim previously held to be anticipated by Ferrante, i.e. claims 1, 5, 6, 9, 10 and 21-25, include a step of moving a saw blade (or cutting tool) in a particular direction. While Ferrante discloses cutting guides with slots for a saw blade and generally discloses that "cutting instruments (osteotomy saws) are well known in the art" (col. 4, lines 60-61), Ferrante does not explicitly or inherently disclose any method steps of using a saw blade (or cutting tool) to cut a bone by moving the saw blade (or cutting tool) in a particular direction, e.g. relative to a long axis of the saw blade, relative to a particular dimension of the cutting guide surface, and/or relative to the medial and lateral sides of the bone.

Thus, Ferrante does not anticipate each and every method step as recited in the above listed claims as amended.

Therefore, Grounds F(1)(a) - F(1)(o) are **withdrawn**.

Grounds G(1)(a) - G(1)(o): PO arguments of paragraph G, pages 68-69 have been considered. PO argues that the anticipation rejection of claims 1-3, 5-12, 21-25, 28-33 and 42-47 should be withdrawn because Woolson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(G), pages 40-43 have been considered. 3PR argues that Woolson still anticipates the claims as amended.

The examiner agrees with 3PR that Woolson still anticipates the claims as amended, but not necessarily for the reasons argued by 3PR. For example, the examiner does not agree with 3PR's arguments regarding slit 52, e.g. "that only one slit, marked 52 in Figs. 4 and 5, is needed for cutting. There is no teaching in Woolson that the surgeon is required to remove his saw from the one slit (marked 52) and place it into the other slit (unmarked) in order to completely resect the anterior femur." The examiner directs 3PR's attention to Fig. 4, wherein the lead line from character reference number 52 points to the slit on the "left" side of the cutting guide, and then to Fig. 5, wherein the lead line from character reference number 52 points to the slit on the "right" side of the cutting guide (with "left" and "right" being defined as the cutting guide is viewed in Fig. 5). Thus, it is clear that Woolson's reference to "a slit 52" (col. 6, line 24) includes the slit on both sides of the cutting guide, and that the disclosure in

Woodson of "a saw 56 cutting through slit 52 makes an initial anterior femoral cut flush with the anterior femoral cortex" (col. 6, lines 26-28) is referring to making the femoral cut by passing the saw blade through slit 52 on both sides of the guide. However, the examiner sees that "the guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of the cutting-surface defining member 50 as shown in Figs. 4 and 5, i.e. either the "left" L-shaped portion of member 50 or the "right" L-shaped portion of member 50. So defined, Woolson anticipates the above listed claims.

Therefore, Grounds G(1)(a) - G(1)(s) are **sustained**.

New Grounds of Rejection

As an initial matter: In the Notice re Defective Paper in *Inter Partes* Reexamination mailed 3/25/11, PO was required, *inter alia*, to provide an explanation of the support in the disclosure of the patent for the changes to the claims made by the amendment paper. PO's Response filed 4/22/11, on p. 44, included the following:

"Explanation of support: Support for the claim amendments can be found at least at Figure 18 and the accompanying text."

Fig. 18 shows an L-shaped tibial cutting guide having a slot 322 through which a cutting tool may be passed. The brief description of Fig. 18 is as follows:

"FIG. 18 is a perspective view of another alternate embodiment of a partial cutting guide for use in the present invention when the patellar tendon, patella, or quad tendon interferes with placement of the cutting guide about the tibia."

The complete "accompanying text" for Fig. 18 is found in col. 19, line 54 through col. 20, line 8, and reads as follows:

"FIG. 18 shows an embodiment of the cutting guide for use when the patellar tendon, the patella, or the quad tendon interferes with the placement of the other cutting guides of the present invention. As shown in FIG. 18, the cutting guide 350 may be directly interconnected with the alignment rod, and positioned on the tibia as hereinbefore set forth. Basically, this embodiment of the invention includes only one cutting guide. The cutting guide 350 and the cutting guide slot 322 may be wider than the previous embodiments to help stabilize the milling bit in operation. In this embodiment, the milling bit may be plunged across the tibia, and then moved therealong. The milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to tissue about the tibia. Additionally, a support member, not shown, could be provided to extend from the cutting guide 350, over and across the tibia to the other side thereof where it could have a slot to capture the milling bit and provide additional support thereto. The reference numerals 338, 360 and 392 correspond to the reference numerals 238, 260 and 292 respectively."

The above has been included so that the record is clear as to the full content of the '541 patent disclosure with regard to the cutting guide of Fig. 18. What can be gleaned from this section of the patent disclosure includes:

1) Cutting guide 350 is for guiding a cutting tool for cutting the proximal end of the tibia;

2) Cutting guide 350 is L-shaped;

2) Slot 322 is wide enough to accommodate a milling bit.

However, there is no support in the patent disclosure for the following:

1) No disclosure as to the relative lengths of each "leg" of the L-shaped guide 350. Assuming that Fig. 18 shows the right proximal tibia, there is no disclosure as to whether the "leg" shown extending along the lateral side of the tibia is longer or shorter than the "leg" shown extending along the anterior side of the tibia.

4) No disclosure of any additional embodiments, e.g. a "mirror image" L-shaped guide designed for placement along the anterior and medial sides of the tibia;

2) No disclosure of using tibial cutting guide 350 in a method of cutting the femur;

3) No disclosure of any similarly shaped (e.g. L-shaped) cutting guides for use on the femur.

Therefore, since PO amended several claims to include subject matter for which there is no support in the patent disclosure, the following new grounds of rejection under 35 USC 112 are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 13-20, 26, 39, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claim 5 -- no written description of a method for a knee implant procedure having a step of positioning a guide along only one of a medial or lateral side and proximate an end of a long bone, wherein at least one guide surface has a longer dimension generally along the one of the medial or the lateral side.

As to claim 13 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side.

As to claim 16 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only one of the medial side or a lateral side of the knee with no portion of the femoral cut guide positioned along the other of a corresponding compartment of the medial side or the lateral side of the femur.

As to claim 26 -- no written description of a method for providing implants, instrumentation and information for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 6 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 21 -- "compartment" in line 8 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 8 "*corresponding* compartment."

As to claim 23 -- "compartment" in line 13 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 13 "*corresponding* compartment."

3PR's proposed 35 USC 112 rejections of claims 9, 10, 24 and 25 are **not adopted** because the terms "medial aspect" and "lateral aspect" are original claim language and are therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 5 and 22 are **not adopted** because the term "at least a portion" is original claim language and is therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 13 and 26 are **not adopted** because the phrase "positioning the femoral cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee" can be understood by one of ordinary skill in the art. Although the specification lacks any disclosure to an L-shaped guide for cutting the femur (addressed above in the 112/1st paragraph section), assuming such a guide were to exist and it was L-shaped similar to the Fig. 18 tibial cutting guide 350 wherein the length of the anterior side "leg" of the guide was shorter than the width of the anterior side of the femur, one of ordinary skill in the art would understand that such an L-shaped femoral cutting guide could "read on" the above recited claim language.

3PR's proposed 35 USC 112 rejections of claims 35-38 and 49-52 are **not adopted.** These claims were originally dependent claims, and have been rewritten in independent form with no changes in any of the claim language (i.e. all of the underlined "new" text in each rewritten claim is verbatim from each original base claim), and the nature of the rewriting does not raise a new question. Per MPEP 2258(II), "If a dependent claim is rewritten as an independent claim in a reexamination proceeding, that independent claim cannot be examined as to 35 USC 112, unless the nature of the rewriting raises a new question."

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,344,541 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

This is a RIGHT OF APPEAL NOTICE (RAN); see MPEP § 2673.02 and § 2674. The decision in this Office action as to the patentability or unpatentability of any original patent claim, any proposed amended claim and any new claim in this proceeding is a FINAL DECISION.

No amendment can be made in response to the Right of Appeal Notice in an *inter partes* reexamination. 37 CFR 1.953(c). Further, no affidavit or other evidence can be submitted in an *inter partes* reexamination proceeding after the right of appeal notice, except as provided in 37 CFR 1.981 or as permitted by 37 CFR 41.77(b)(1). 37 CFR 1.116(f).

Each party has a **thirty-day or one-month time period, whichever is longer,** to file a notice of appeal. The patent owner may appeal to the Board of Patent Appeals and Interferences with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent by filing a notice of appeal and paying the fee set forth in 37 CFR 41.20(b)(1). The third party requester may appeal to the Board of Patent Appeals and Interferences with respect to any decision favorable to the patentability of any original or proposed amended or new claim of the patent by filing a notice of appeal and paying the fee set forth in 37 CFR 41.20(b)(1).

In addition, a patent owner who has not filed a notice of appeal may file a notice of cross appeal within **fourteen days of service** of a third party requester's timely filed notice of appeal and pay the fee set forth in 37 CFR 41.20(b)(1). A third party requester who has not filed a notice of appeal may file **a notice of cross appeal within fourteen days of service** of a patent owner's timely filed notice of appeal and pay the fee set forth in 37 CFR 41.20(b)(1).

Any appeal in this proceeding must identify the claim(s) appealed, and must be signed by the patent owner (for a patent owner appeal) or the third party requester (for a third party requester appeal), or their duly authorized attorney or agent.

Any party that does not file a timely notice of appeal or a timely notice of cross appeal will lose the right to appeal from any decision adverse to that party, but will not lose the right to file a respondent brief and fee where it is appropriate for that party to do so. If no party files a timely appeal, the reexamination prosecution will be terminated, and the Director will proceed to issue and publish a certificate under 37 CFR 1.997 in accordance with this Office action.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

By EFS: Registered users may submit via electronic filing system EFS-Web, at https://efs.uspto.gov/efile/myportal/efs-registered

By Mail to: Mail Stop *Inter Partes* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Attn: Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1)(i) (C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any paper filed by either the patent owner or the 3PR ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Other useful telephone numbers:

Reexamination Practice	(571) 272-7703
Reexamination Facsimile Transmission No.	(571) 273-9900

David O. Reip
Primary Examiner
Central Reexamination Unit

Conferee

Conferee

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,469	10/15/2010	7344541	BIOMET1	7743

7590 08/29/2011

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EXAMINER	
REIP, DAVID OWEN	
ART UNIT	**PAPER NUMBER**
3993	

MAIL DATE	DELIVERY MODE
08/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

TROUTMAN SANDERS LLP
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ATLANTA, GA 30308-2216

Date:

MAILED

AUG 29 2011

CENTRAL REEXAMINATION UNIT

Transmittal of Communication to Third Party Requester
Inter Partes Reexamination

REEXAMINATION CONTROL NO. : 95001469
PATENT NO. : 7344541
TECHNOLOGY CENTER : 3999
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified Reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

PTOL-2070(Rev.07-04)

ACTION CLOSING PROSECUTION (37 CFR 1.949)	Control No.	Patent Under Reexamination
	95/001,469	7344541
	Examiner	Art Unit
	DAVID O. REIP	3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:
Patent Owner on 24 January 2011 AND 22 APRIL 2011
Third Party(ies) on 23 February 2011 AND 23 MAY 2011

Patent owner may once file a submission under 37 CFR 1.951(a) within 1 month(s) from the mailing date of this Office action. Where a submission is filed, third party requester may file responsive comments under 37 CFR 1.951(b) within 30-days (not extendable- 35 U.S.C. § 314(b)(2)) from the date of service of the initial submission on the requester. **Appeal cannot be taken from this action.** Appeal can only be taken from a Right of Appeal Notice under 37 CFR 1.953.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892
2. ☒ Information Disclosure Citation, PTO/SB/08
3. ☐ _____

PART II. SUMMARY OF ACTION:

1a. ☒ Claims 1-54 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled.
3. ☐ Claims _____ are confirmed. [Unamended patent claims]
4. ☐ Claims _____ are patentable. [Amended or new claims]
5. ☒ Claims 1-54 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The drawings filed on _____ ☐ are acceptable ☐ are not acceptable.
8 ☐ The drawing correction request filed on _____ is: ☐ approved. ☐ disapproved.
9 ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has: ☐ been received. ☐ not been received. ☐ been filed in Application/Control No _____
10. ☐ Other _____

Inter Partes Reexamination

Background

On 10/15/10, the request for *Inter Partes* reexamination of U.S. Pat. No. 7,344,541 was filed by the third party requester ("3PR").

On 11/10/10, the Decision granting reexamination was mailed.

On 11/23/10, a non-final Office action was mailed. All 54 patent claims were rejected on various grounds, as proposed by 3PR and adopted by the examiner.

On 1/24/11, patent owner ("PO") filed a timely response which included claim amendments. It was noted that the amendment did not comply with 37 CFR 1.530 and was therefore not entered.

On 2/23/11, 3PR filed Comments in response to PO's 1/24/11 response and amendment.

On 3/25/11, a Notice re Defective Paper in *Inter Partes* Reexamination was mailed wherein the defects in PO's 1/24/11 response and amendment were noted. PO was given 30-days or one month (whichever was longer) to file a corrected response and amendment.

On 4/22/11, PO filed a timely Response to Notice of Defective Paper. It is noted that PO's response included only a page 1 Transmittal notice, pages 2-43 of corrected claim amendments, and a page 44 "Status of claims and support for claim changes." PO did not resubmit their Remarks section. Therefore, the examiner has assumed PO's remarks are the same as those on pages 48-73 of PO's 1/24/11 response. With that

assumption, it is then noted that PO's complete response includes pages that are numbered 1-44 and 48-73, and that there are no pages numbered 45-47.

On 5/23/11, 3PR filed Comments in response to PO's response to Notice re Defective Paper.

Previous Prosecution

In the request, 3PR proposed the following grounds of rejection (see 3PR's Table of Contents, pages iv-xi):

Grounds A(1)(a) - A(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelson.

Grounds A(2)(a) - A(2)(s): Claims 1-54 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Protek F/S Modular.

Grounds A(3)(a) - A(3)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 103 as being obvious over Samuelson in view of Matsen.

Grounds B(1)(a) - B(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102 as being anticipated by Biomet Brochure.

Grounds C(1)(a) - C(1)(e): Claims 1-5, 8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark II.

Grounds D(1)(a) - D(1)(s): Claims 1-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Protek F/S Modular.

Grounds E(1)(a) - E(1)(o): Claims 1-12, 21-25, 28-33 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen.

Grounds F(1)(a) - F(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferrante.

Grounds G(1)(a) - G(1)(o): Claims 1-12, 21-25, 27-34 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolson.

In the non-final Office action mailed 11/23/10, the examiner adopted all proposed rejections except the following:

As to Grounds A(1)(a) - A (1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds A(2)(a) - A(2)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds B(1)(a) - B(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds D(1)(a) - D(1)(s): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds F(1)(a) - F(1)(o): The proposed rejections of claims 30 and 44 were not adopted.

As to Grounds G(1)(a) - G(1)(o): The proposed rejections of claims 4, 27, 34, 41 and 48 were not adopted.

PO's Amendment, 3PR's Response, and Examiner's decision

Grounds A(1)(a) - A(1)(s): PO arguments of paragraph A, pages 53-56 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Samuelson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(A), pages 13-20 have been considered. 3PR argues that Samuelson still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(A), pages 13-20 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Samuelson, e.g. as depicted in 3PR's Fig. 11A mark-up on p.15 of their Comments, wherein swing arm 334 along with arm support 352 defines "the guide surface." Thus, said "the guide surface," when placed in the operative position, would be generally along the medial or lateral side of the long bone being cut *with no other portion of the guide surface positioned along the corresponding compartment of the other of the medial side or the lateral side of the long bone*, as recited in e.g. amended claim 1.

Therefore, Grounds A(1)(a) - A(1)(s) are **sustained**.

Grounds A(2)(a) - A(2)(s) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para. IV(A), pages 43-45 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds A(3)(a) - A(3)(o) are **sustained** for substantially the same reason as discussed above for Grounds A(1)(a) - A(1)(s), and for the reasons set forth in para. IV(B), pages 45-46 of 3PR's 2/23/11 Comments, which are hereby incorporated by reference.

Grounds B(1)(a) - B(1)(s): PO arguments of paragraph B, pages 56-59 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Biomet Brochure does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(B), pages 20-25 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(B), pages 20-25 of their 2/23/11 Comments, which are hereby incorporated by reference. "The guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of one of the guides of Biomet Brochure, e.g. as depicted in 3PR's drawings on p.22 of their Comments. Additionally, as argued by 3PR, Biomet Brochure at 18 expressly discloses placing only the medial cutting guide arm into the operative position because of the position of the patellar tendon.

Therefore, Grounds B(1)(a) - B(1)(s) are **sustained**.

Grounds C(1)(a) - C(1)(e): PO arguments of paragraph C, pages 59-61 have been considered. PO argues that the anticipation rejection of claims 1-5, 8, 21 and 22 should be withdrawn because Mark II does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(C), pages 25-28 have been considered. 3PR argues that Biomet Brochure still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(C), pages 25-28 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the anterior view drawing at step 5 of the Proximal Tibia Osteotomy shows that with both cutting guide arms retracted, a portion of each arm is positioned along less than one-half a width of the anterior side. Also, as shown at step 7, the medial cutting guide arm is wrapped around the medial tibia and the tibia is saw cut in at least two directions -- 1) anterior to posterior, substantially perpendicular to a longitudinal axis of the anterior cutting guide; and 2) medial to lateral, substantially perpendicular to the curved axis of the medial cutting guide arm.

Therefore, Grounds C(1)(a) - C(1)(e) are **sustained**.

Grounds D(1)(a) - D(1)(s): PO arguments of paragraph D, pages 61-64 have been considered. PO argues that the anticipation rejection of claims 1-29, 31-43 and 45-54 should be withdrawn because Protek F/S Modular does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(D), pages 28-33 have been considered. 3PR argues that Protek F/S Modular still anticipates the claims as amended.

The examiner agrees with 3PR for the reasons set forth in para. III(D), pages 28-33 of their 2/23/11 Comments, which are hereby incorporated by reference. As argued by 3PR, the Step 2: Resection of the Proximal Tibia on p. 18 of 57 expressly discloses wrapping only the medial cutting guide arm around the medial tibia because the position of the patellar tendon precludes the use of the cutting guide arm on the lateral side. Thus, for example with respect to claim 1, Protek F/S Modular shows "at least a portion of the at least one guide surface is positioned along only one of a medial side or a lateral side and proximate an end of a long bone of a knee joint with no other portion of the guide surface positioned along a corresponding compartment of the other of the medial side or the lateral side of the long bone" as recited.

Therefore, Grounds D(1)(a) - D(1)(s) are **sustained**.

Grounds E(1)(a) - E(1)(o): PO arguments of paragraph E, pages 64-66 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 28-33 and 42-47 should be withdrawn because Matsen does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(E), pages 34-37 have been considered. 3PR argues that Matsen still anticipates the claims as amended.

The examiner agrees with PO. While the Matsen guide as shown in Figs. 19-21 *could* be placed to cover the medial or lateral side of the bone and only a portion of the

anterior side as argued by 3PR, no explicit disclosure of such placement is made in Matsen. Thus, Matsen does not *anticipate* (i.e. expressly or inherently disclose) each and every method step as recited in the above listed claims as amended.

Therefore, Grounds E(1)(a) - E(1)(o) are **withdrawn**.

Grounds F(1)(a) - F(1)(o): PO arguments of paragraph F, pages 66-68 have been considered. PO argues that the anticipation rejection of claims 1-12, 21-25, 27-29, 31-34, 41-43 and 45-48 should be withdrawn because Ferrante does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(F), pages 38-40 have been considered. 3PR argues that Ferrante still anticipates the claims as amended.

The examiner agrees with PO, but not necessarily for the reasons as argued by PO. Upon reconsideration, the examiner notes that each independent claim previously held to be anticipated by Ferrante, i.e. claims 1, 5, 6, 9, 10 and 21-25, include a step of moving a saw blade (or cutting tool) in a particular direction. While Ferrante discloses cutting guides with slots for a saw blade and generally discloses that "cutting instruments (osteotomy saws) are well known in the art" (col. 4, lines 60-61), Ferrante does not explicitly or inherently disclose any method steps of using a saw blade (or cutting tool) to cut a bone by moving the saw blade (or cutting tool) in a particular direction, e.g. relative to a long axis of the saw blade, relative to a particular dimension of the cutting guide surface, and/or relative to the medial and lateral sides of the bone.

Thus, Ferrante does not anticipate each and every method step as recited in the above listed claims as amended.

Therefore, Grounds F(1)(a) - F(1)(o) are **withdrawn**.

Grounds G(1)(a) - G(1)(o): PO arguments of paragraph G, pages 68-69 have been considered. PO argues that the anticipation rejection of claims 1-3, 5-12, 21-25, 28-33 and 42-47 should be withdrawn because Woolson does not teach each and every element as recited in the claims as amended.

3PR's Comments of paragraph III(G), pages 40-43 have been considered. 3PR argues that Woolson still anticipates the claims as amended.

The examiner agrees with 3PR that Woolson still anticipates the claims as amended, but not necessarily for the reasons argued by 3PR. For example, the examiner does not agree with 3PR's arguments regarding slit 52, e.g. "that only one slit, marked 52 in Figs. 4 and 5, is needed for cutting. There is no teaching in Woolson that the surgeon is required to remove his saw from the one slit (marked 52) and place it into the other slit (unmarked) in order to completely resect the anterior femur." The examiner directs 3PR's attention to Fig. 4, wherein the lead line from character reference number 52 points to the slit on the "left" side of the cutting guide, and then to Fig. 5, wherein the lead line from character reference number 52 points to the slit on the "right" side of the cutting guide (with "left" and "right" being defined as the cutting guide is viewed in Fig. 5). Thus, it is clear that Woolson's reference to "a slit 52" (col. 6, line 24) includes the slit on both sides of the cutting guide, and that the disclosure in

Woodson of "a saw 56 cutting through slit 52 makes an initial anterior femoral cut flush with the anterior femoral cortex" (col. 6, lines 26-28) is referring to making the femoral cut by passing the saw blade through slit 52 on both sides of the guide. However, the examiner sees that "the guide surface," "the at least one guide surface," "the cutting guide," etc. as recited in the claims can be defined by only a portion of the cutting-surface defining member 50 as shown in Figs. 4 and 5, i.e. either the "left" L-shaped portion of member 50 or the "right" L-shaped portion of member 50. So defined, Woolson anticipates the above listed claims.

Therefore, Grounds G(1)(a) - G(1)(s) are **sustained**.

New Grounds of Rejection

As an initial matter: In the Notice re Defective Paper in *Inter Partes* Reexamination mailed 3/25/11, PO was required, *inter alia*, to provide an explanation of the support in the disclosure of the patent for the changes to the claims made by the amendment paper. PO's Response filed 4/22/11, on p. 44, included the following:

"Explanation of support: Support for the claim amendments can be found at least at Figure 18 and the accompanying text."

Fig. 18 shows an L-shaped tibial cutting guide having a slot 322 through which a cutting tool may be passed. The brief description of Fig. 18 is as follows:

"FIG. 18 is a perspective view of another alternate embodiment of a partial cutting guide for use in the present invention when the patellar tendon, patella, or quad tendon interferes with placement of the cutting guide about the tibia."

The complete "accompanying text" for Fig. 18 is found in col. 19, line 54 through col. 20, line 8, and reads as follows:

"FIG. 18 shows an embodiment of the cutting guide for use when the patellar tendon, the patella, or the quad tendon interferes with the placement of the other cutting guides of the present invention. As shown in FIG. 18, the cutting guide 350 may be directly interconnected with the alignment rod, and positioned on the tibia as hereinbefore set forth. Basically, this embodiment of the invention includes only one cutting guide. The cutting guide 350 and the cutting guide slot 322 may be wider than the previous embodiments to help stabilize the milling bit in operation. In this embodiment, the milling bit may be plunged across the tibia, and then moved therealong. The milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to tissue about the tibia. Additionally, a support member, not shown, could be provided to extend from the cutting guide 350, over and across the tibia to the other side thereof where it could have a slot to capture the milling bit and provide additional support thereto. The reference numerals 338, 360 and 392 correspond to the reference numerals 238, 260 and 292 respectively."

The above has been included so that the record is clear as to the full content of the '541 patent disclosure with regard to the cutting guide of Fig. 18. What can be gleaned from this section of the patent disclosure includes:

1) Cutting guide 350 is for guiding a cutting tool for cutting the proximal end of the tibia;

2) Cutting guide 350 is L-shaped;

2) Slot 322 is wide enough to accommodate a milling bit.

However, there is no support in the patent disclosure for the following:

1) No disclosure as to the relative lengths of each "leg" of the L-shaped guide 350. Assuming that Fig. 18 shows the right proximal tibia, there is no disclosure as to whether the "leg" shown extending along the lateral side of the tibia is longer or shorter than the "leg" shown extending along the anterior side of the tibia.

4) No disclosure of any additional embodiments, e.g. a "mirror image" L-shaped guide designed for placement along the anterior and medial sides of the tibia;

2) No disclosure of using tibial cutting guide 350 in a method of cutting the femur;

3) No disclosure of any similarly shaped (e.g. L-shaped) cutting guides for use on the femur.

Therefore, since PO amended several claims to include subject matter for which there is no support in the patent disclosure, the following new grounds of rejection under 35 USC 112 are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 13-20, 26, 39, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claim 5 -- no written description of a method for a knee implant procedure having a step of positioning a guide along only one of a medial or lateral side and proximate an end of a long bone, wherein at least one guide surface has a longer dimension generally along the one of the medial or the lateral side.

As to claim 13 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side.

As to claim 16 -- no written description of a method for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only one of the medial side or a lateral side of the knee with no portion of the femoral cut guide positioned along the other of a corresponding compartment of the medial side or the lateral side of the femur.

As to claim 26 -- no written description of a method for providing implants, instrumentation and information for a knee implant procedure having a step of positioning a *femoral* cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 6 -- "compartment" in line 6 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 6 "*corresponding* compartment."

As to claim 21 -- "compartment" in line 8 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 8 "*corresponding* compartment."

As to claim 23 -- "compartment" in line 13 lacks antecedent basis in the claim. There is no earlier recitation of a "compartment" to relate to the line 13 "*corresponding* compartment."

3PR's proposed 35 USC 112 rejections of claims 9, 10, 24 and 25 are **not adopted** because the terms "medial aspect" and "lateral aspect" are original claim language and are therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 5 and 22 are **not adopted** because the term "at least a portion" is original claim language and is therefore not subject to review under 112.

3PR's proposed 35 USC 112 rejections of claims 13 and 26 are **not adopted** because the phrase "positioning the femoral cut guide to extend toward and generally along only a portion of an anterior side of the femur and only one of a medial side or a lateral side of the knee" can be understood by one of ordinary skill in the art. Although the specification lacks any disclosure to an L-shaped guide for cutting the femur (addressed above in the 112/1st paragraph section), assuming such a guide were to exist and it was L-shaped similar to the Fig. 18 tibial cutting guide 350 wherein the length of the anterior side "leg" of the guide was shorter than the width of the anterior side of the femur, one of ordinary skill in the art would understand that such an L-shaped femoral cutting guide could "read on" the above recited claim language.

3PR's proposed 35 USC 112 rejections of claims 35-38 and 49-52 are **not adopted.** These claims were originally dependent claims, and have been rewritten in independent form with no changes in any of the claim language (i.e. all of the underlined "new" text in each rewritten claim is verbatim from each original base claim), and the nature of the rewriting does not raise a new question. Per MPEP 2258(II), "If a dependent claim is rewritten as an independent claim in a reexamination proceeding, that independent claim cannot be examined as to 35 USC 112, unless the nature of the rewriting raises a new question."

Information Disclosure Statements

Per MPEP 2256, where patents, publications, and other such items of information are submitted by a party (patent owner or third party requester) in

compliance with the requirements of the rules, the requisite degree of consideration to be given to such information will normally be limited by the degree to which the party filing the information citation has explained the content and relevance of the information. The initials of the examiner placed adjacent the citations on the form PTO/SB/08A and 08B or its equivalent, without an indication to the contrary in the record, do not signify that the information has been considered by the examiner any further than to the extent noted above. As to patents and printed publications of record in the patent file from earlier examination, it is pointed out that, even the degree of consideration of information from the patent file and its parent files is dependent on the availability of the information. Thus, if references other than U.S. patents and U.S. patent publications were discarded at the time the patent was issued and were not scanned into the Image File Wrapper, then what was said about the references in the patent's record is the full extent of consideration, unless otherwise indicated.

The information disclosure statement filed on 2/25/11 contains citations of Court Proceedings listed on "Substitute for Form 1449/PTO" forms. The cited Court Proceedings do not constitute prior art; consequently, said forms does not appear to be a proper vehicle for notifying the PTO of this information. However, the copies of these Court Proceedings have been received and made of record in the file and are acknowledged as having been filed as Information From Related Litigation as set forth in MPEP 2001.06(c). Further, while items such as declarations and court documents

are evidence, they are not "prior art" as defined in 37 CFR 1.510 and will not be placed on the face of the patent. Thus, the items are lined through.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner's response is set by statute. 35 USC 314(b)(3).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.985 to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,344,541 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP § 2686 and 2686.04.

Service of Papers

Any paper filed by either the patent owner or the third party requester ***must be served*** on the other party in the reexamination proceeding in the manner provided by 37 CFR 1.248. See 37 CFR 1.903 and MPEP 2666.06.

This is an ACTION CLOSING PROSECUTION (ACP); see MPEP § 2671.02.

(1) Pursuant to 37 CFR 1.951(a), the patent owner may once file written comments limited to the issues raised in the reexamination proceeding and/or present a proposed amendment to the claims which amendment will be subject to the criteria of 37 CFR 1.116 as to whether it shall be entered and considered. Such comments and/or proposed amendments must be filed within a time period of 30 days or one month (whichever is longer) from the mailing date of this action. Where the patent owner files such comments and/or a proposed amendment, the third party requester may once file comments under 37 CFR 1.951(b) responding to the patent owner's submission within 30 days from the date of service of the patent owner's submission on the third party requester.

(2) If the patent owner does not timely file comments and/or a proposed amendment pursuant to 37 CFR 1.951(a), then the third party requester is precluded from filing comments under 37 CFR 1.951(b).

(3) Appeal **cannot** be taken from this action, since it is not a final Office action.

All correspondence relating to this *inter partes* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Inter Partes* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

David O. Reip
Primary Examiner
Central Reexamination Unit
(571) 272-4702

Conferee

Conferee

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,469	10/15/2010	7344541	BIOMET1	7743

7590 09/04/2013

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EXAMINER	
REIP, DAVID OWEN	

ART UNIT	PAPER NUMBER
3993	

MAIL DATE	DELIVERY MODE
09/04/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Transmittal of Communication to Third Party Requester *Inter Partes* Reexamination	Control No.	Patent Under Reexamination	
	95/001,469	7344541	
	Examiner	Art Unit	
	DAVID O. REIP	3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

TROUTMAN SANDERS LLP
5200 BANK OF AMERICA PLAZA
600 PEACHTREE STREET, N.E., SUITE 5200
ATLANTA, GA 30308-2216

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination prceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

Inter Partes Reexamination Examiner's Answer	**Application No.** 95/001,469	**Applicant(s)** 7344541	
	Examiner DAVID O. REIP	**Art Unit** 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Incorporation by Reference of the Right of Appeal Notice
The Right of Appeal Notice (RAN) mailed on 21 May 2012, including all of the grounds of rejection, determinations of patentability, and explanations set forth in the RAN is incorporated by reference. Every ground of rejection and every determination not to make a proposed rejection set forth in the RAN are being maintained by the examiner.

This examiner's answer does not contain any new ground of rejection and any new determination not to make a proposed rejection.

Status of Amendment After Action Closing Prosecution
The amendment(s) filed on _____ has/have been entered.
The amendment(s) filed on 29 September 2011 has/have not been entered.

Period for providing a Rebuttal Brief
Appellant(s) is/are given a period of ONE MONTH from the mailing date of this examiner's answer within which to file a rebuttal brief in response to the examiner's answer. Prosecution otherwise remains closed.

The rebuttal brief of the patent owner may be directed to the examiner's answer and/or any respondent's brief. The rebuttal brief of the third party requester(s) may be directed to the examiner's answer and/or the respondent's brief of the patent owner. The rebuttal brief must (1) clearly identify each issue, and (2) point out *where* the issue was raised in the examiner's answer and/or in the respondent's brief. In addition, the rebuttal brief must be limited to issues raised in the examiner's answer or in the respondent's brief. The time for filing the rebuttal brief may not be extended. No further submission (other than the rebuttal brief(s)) will be considered, and any such submission will be treated in accordance with 37 CFR 1.939 and MPEP 2667.

☐ Attachment(s)
_____

☐ Other:
/David Reip/ David Reip, Patent Reexamination Specialist

Conferees: /Michael W. Phillips/ Michael Phillips

_____/Jimmy G. Foster/ Jimmy Foster

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at one of the following addresses:

Please mail any communications to:
Attn: Mail Stop "Inter partes Reexam"
Central Reexamination Unit
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Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria VA 22314

Please FAX any communications to: (571) 273-9900

Litigation Search Report CRU 3999

Reexam Control No. 95/001,469

To: David Reip Location: CRU Art Unit: 3993 Date: 8/14/13 Case Serial Number: 95/001,469	From: Alicia Kelley-Collier Location: CRU 3999 MDE 5A74 Phone: (571) 272-6059 alicia.kelley@uspto.gov

Search Notes

U.S. Patent No. **7,344,541**

1) I performed a KeyCite Search in Westlaw, which retrieves all history on the patent including any litigation.

2) I performed a search on the patent in Lexis CourtLink for any open dockets or closed cases.

3) I performed a search in Lexis in the Federal Courts and Administrative Materials databases for any cases found.

4) I performed a search in Lexis in the IP Journal and Periodicals database for any articles on the patent.

5) I performed a search in Lexis in the news databases for any articles about the patent or any articles about litigation on this patent.

Litigation involving this patent was found.

3:10cv463 Open 12/09/2010 ORDER granting Motion to Stay action pending re-examination of US Patent. **10/28/2011** Joint STIPULATION in Regards to Stay Pending Re-examination and November 2, 2011 Telephonic Status Conference by Defendant DePuy Orthopaedics Inc. **10/31/2011** ORDER re Joint STIPULATION in Regards to Stay Pending Re-examination and November 2, 2011 Telephonic Status Conference filed by DePuy Orthopaedics Inc. Telephonic Status Conference scheduled for 11/2/2011 is vacated.

3:10cv465 Open 11/11/2010 MOTION to Stay Action Pending Reexamination of the 541. **12/08/2010** ORDER granting 34 Motion to Stay. Case STAYED pending the USPTO's decision. Parties to file a status report by 2/8/2011 OR when the USPTO issues a decision, whichever first occurs.

1:10cv4459 Closed

1:10cv2103 Closed

1:08cv1566 Closed

EXHIBIT A

U.S. Patent No. 7,344,541 to Haines *et al.*, entitled METHODS AND APPARATUS FOR FEMORAL AND TIBIAL RESECTION, filed on January 13, 2004, and issued on March 18, 2008 ("the '541 Patent)

US007344541B2

(12) **United States Patent**
Haines et al.

(10) **Patent No.: US 7,344,541 B2**
(45) **Date of Patent: Mar. 18, 2008**

(54) **METHODS AND APPARATUS FOR FEMORAL AND TIBIAL RESECTION**

(75) Inventors: **Timothy G. Haines**, New Brighton, MN (US); **David B. Goldstein**, Cream Ridge, NJ (US)

(73) Assignee: **Hudson Surgical Design, Inc.**, Cream Ridge, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 478 days.

(21) Appl. No.: **10/756,817**

(22) Filed: **Jan. 13, 2004**

(65) **Prior Publication Data**

US 2005/0055028 A1 Mar. 10, 2005

Related U.S. Application Data

(60) Continuation of application No. 09/799,325, filed on Mar. 5, 2001, now Pat. No. 6,695,848, which is a continuation-in-part of application No. 09/261,528, filed on Mar. 3, 1999, now Pat. No. 6,197,064, which is a continuation of application No. 08/892,286, filed on Jul. 14, 1997, now Pat. No. 5,879,354, which is a division of application No. 08/649,465, filed on May 17, 1996, now Pat. No. 5,755,803, which is a continuation-in-part of application No. 08/603,582, filed on Feb. 20, 1996, now Pat. No. 5,810,827, and a continuation-in-part of application No. 08/479,363, filed on Jun. 7, 1995, now Pat. No. 5,643,272, which is a continuation-in-part of application No. 08/342,143, filed on Nov. 18, 1994, now Pat. No. 5,597,379, which is a continuation-in-part of application No. 08/300,379, filed on Sep. 2, 1994, now Pat. No. 5,514,139.

(51) **Int. Cl.**
A61B 17/58 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **606/88**; 606/86; 606/87

(58) **Field of Classification Search** 606/79, 606/82, 86, 88; 623/20.14–20.36
See application file for complete search history.

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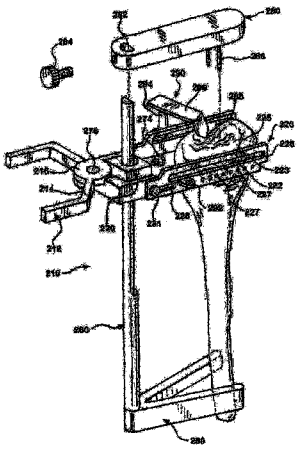
Primary Examiner—Eduardo C. Robert
Assistant Examiner—Mary Hoffman
(74) *Attorney, Agent, or Firm*—Patterson, Thuente, Skaar & Christensen, P.A.

(57) **ABSTRACT**

Methods and apparatus for knee arthroplasty utilize components including an alignment device, a single medially or laterally located guidance device, and a cutting device for use in preparing the bones of a knee joint to receive knee arthroplasty implants. The alignment device is used to locate and orient the guidance device adjacent the medial or lateral side of a long bone of a knee joint. The cutting device is engaged with the guidance device and plunged across the end of the long bone to create a resected surface with respect to which a knee arthroplasty implant will be fixed. In one embodiment, the cutting tool guidance device extends less than about half way across the end of a long bone of a knee joint.

54 Claims, 40 Drawing Sheets



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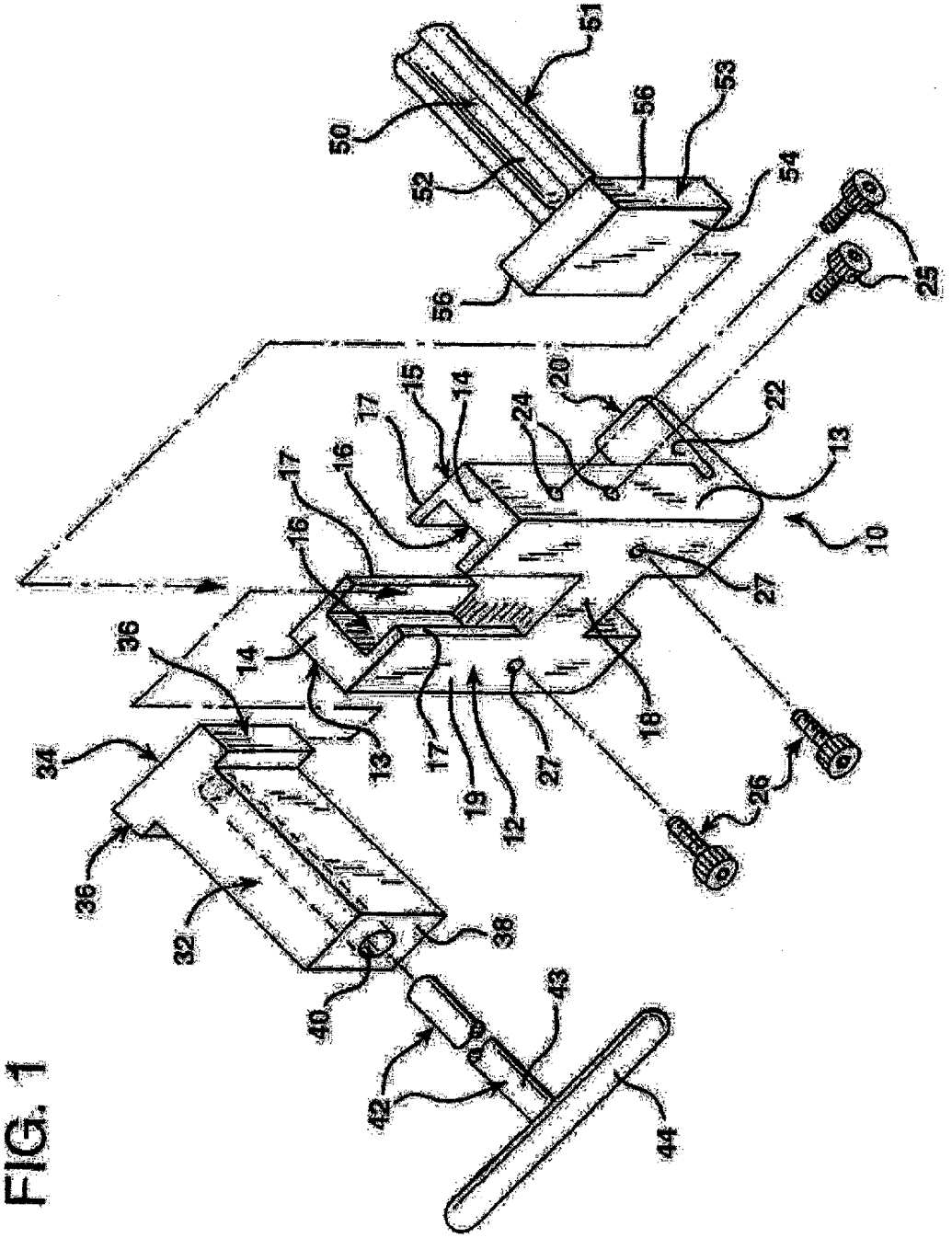
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FIG. 1

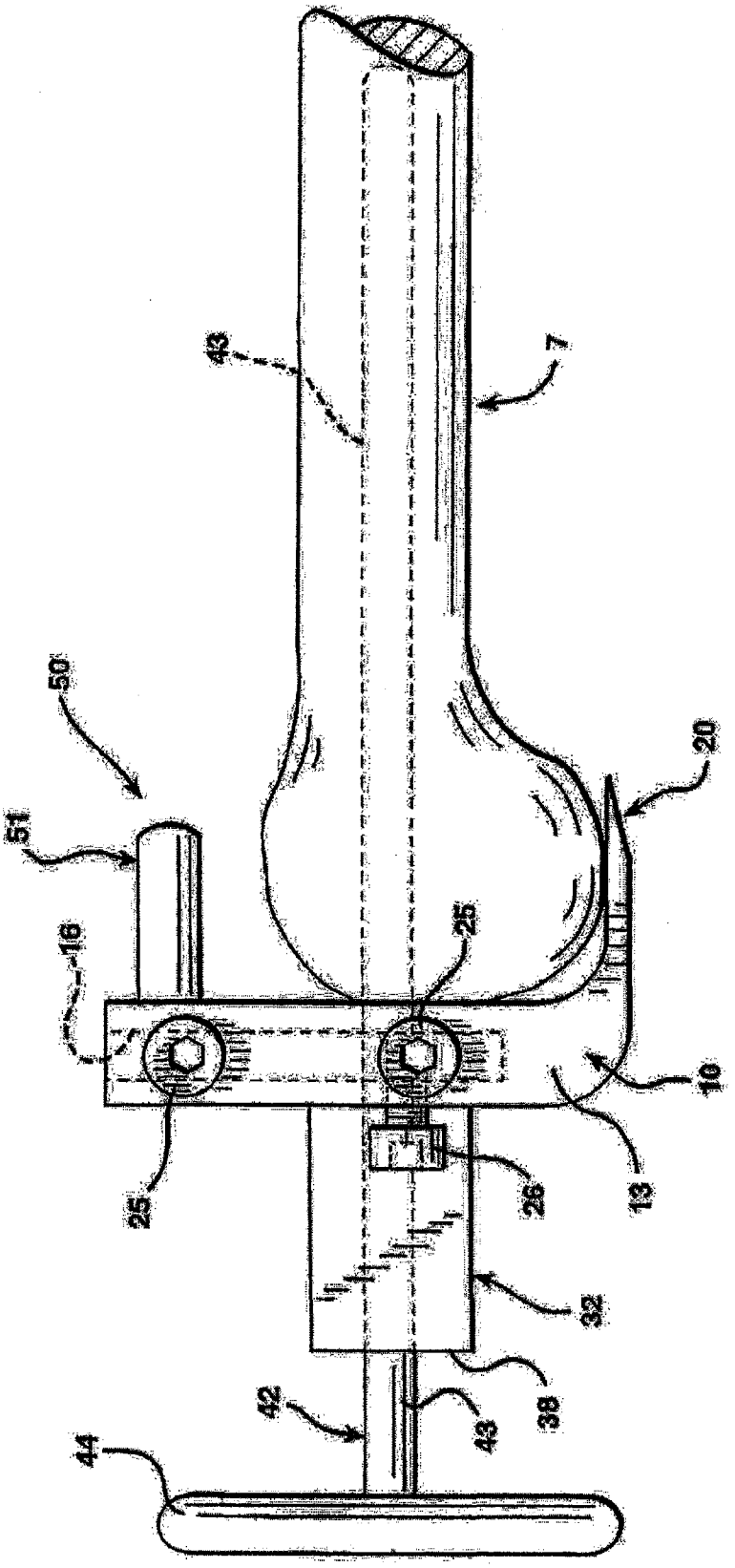

FIG. 2

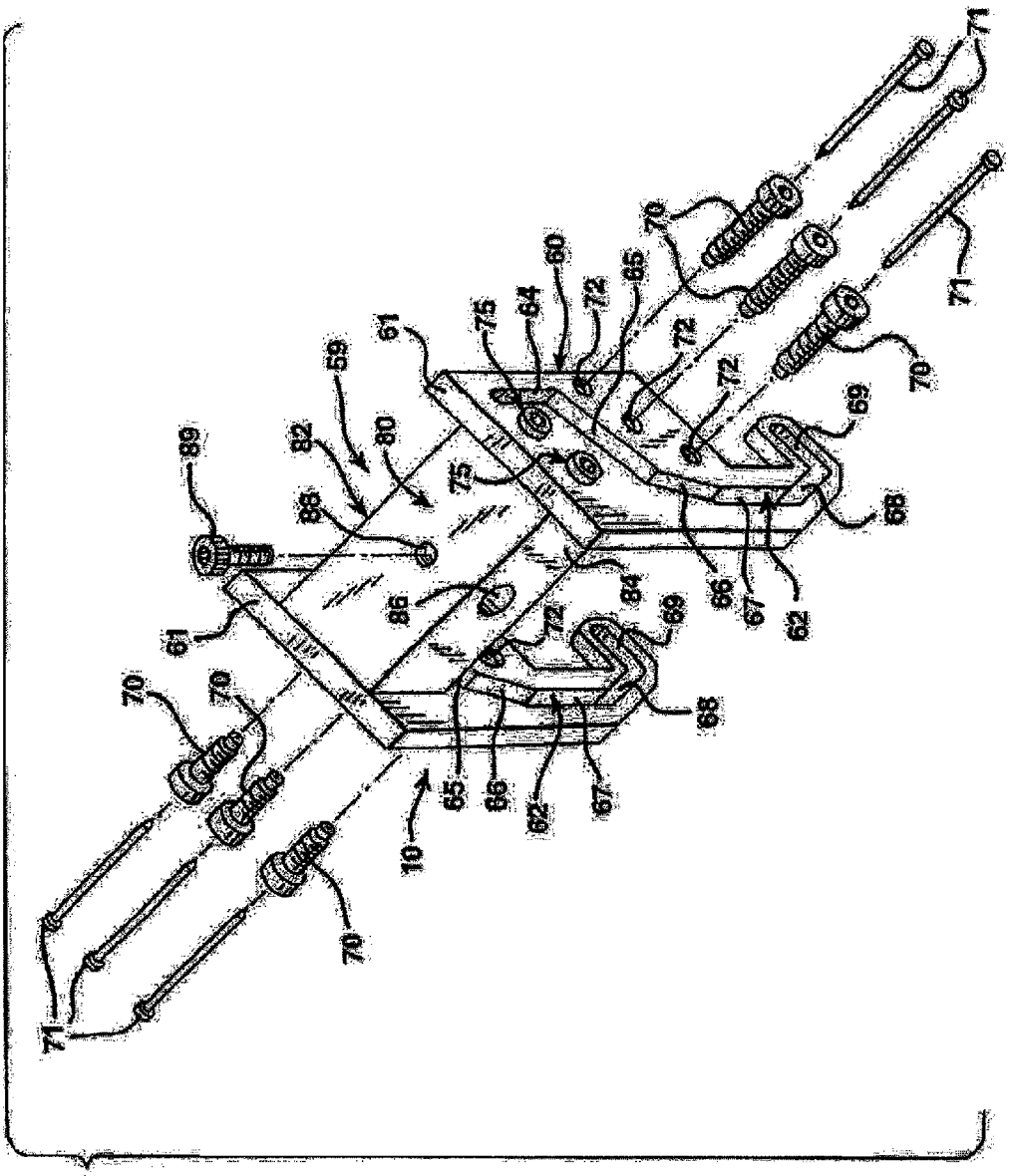
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FIG. 3

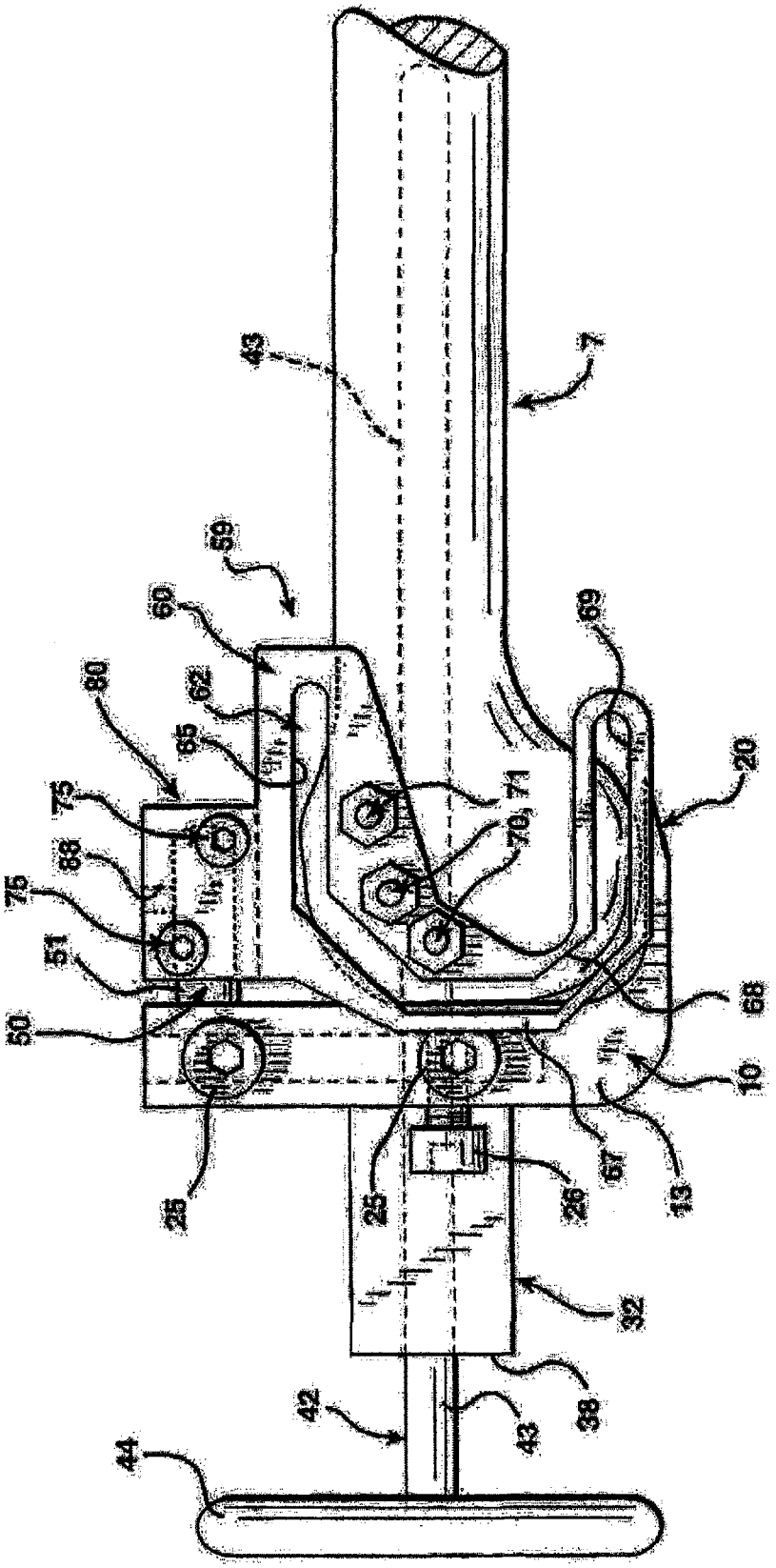
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FIG. 4

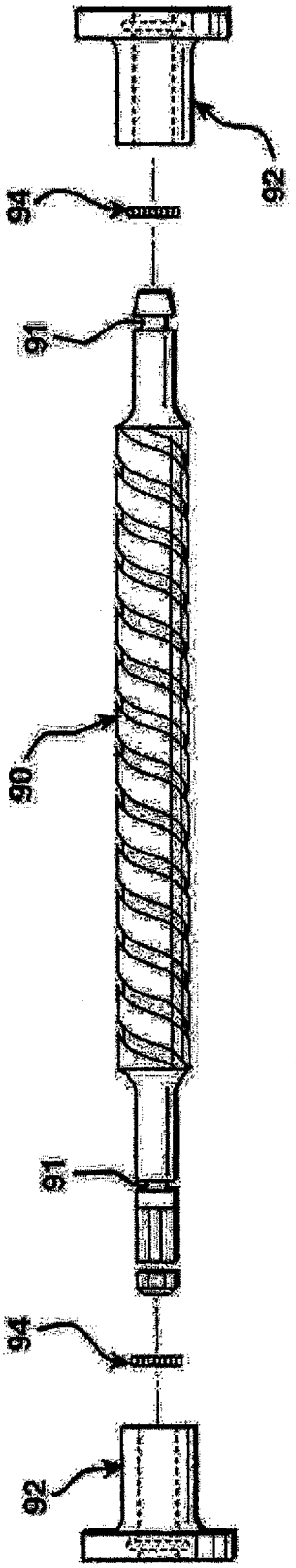

FIG. 5

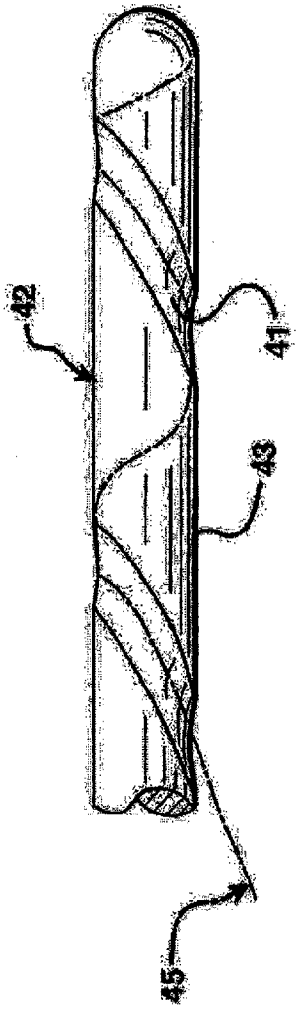

FIG. 7

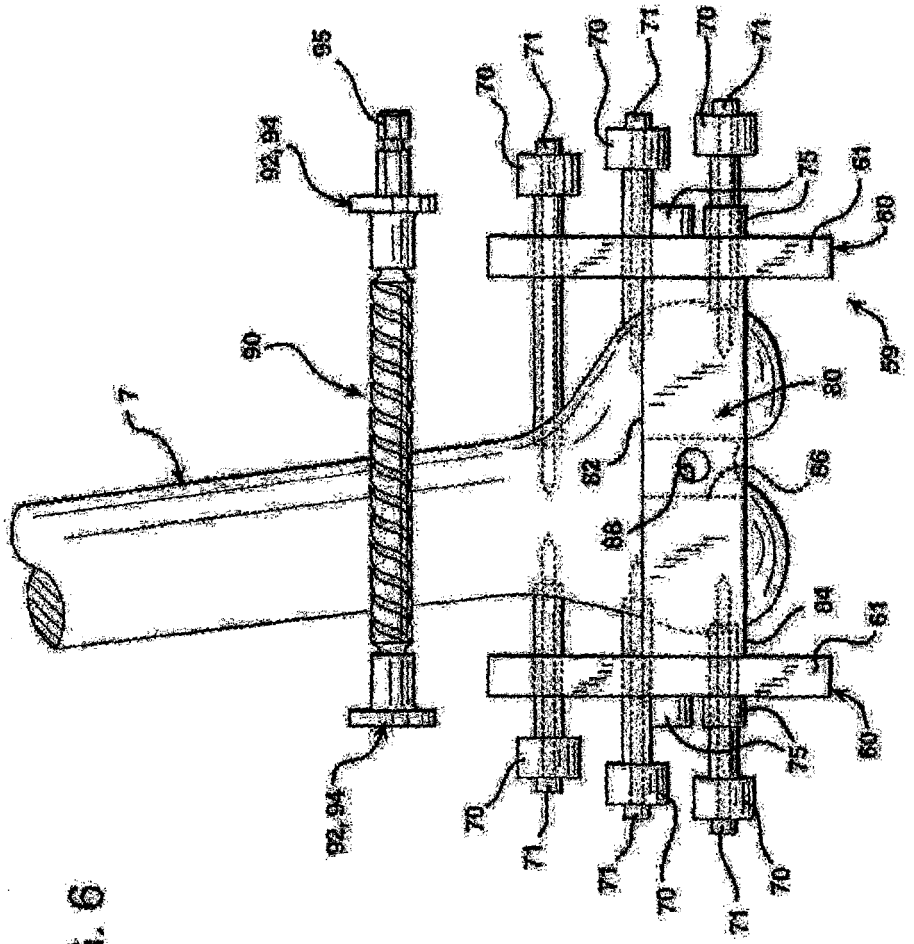
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FIG. 6

FIG. 8

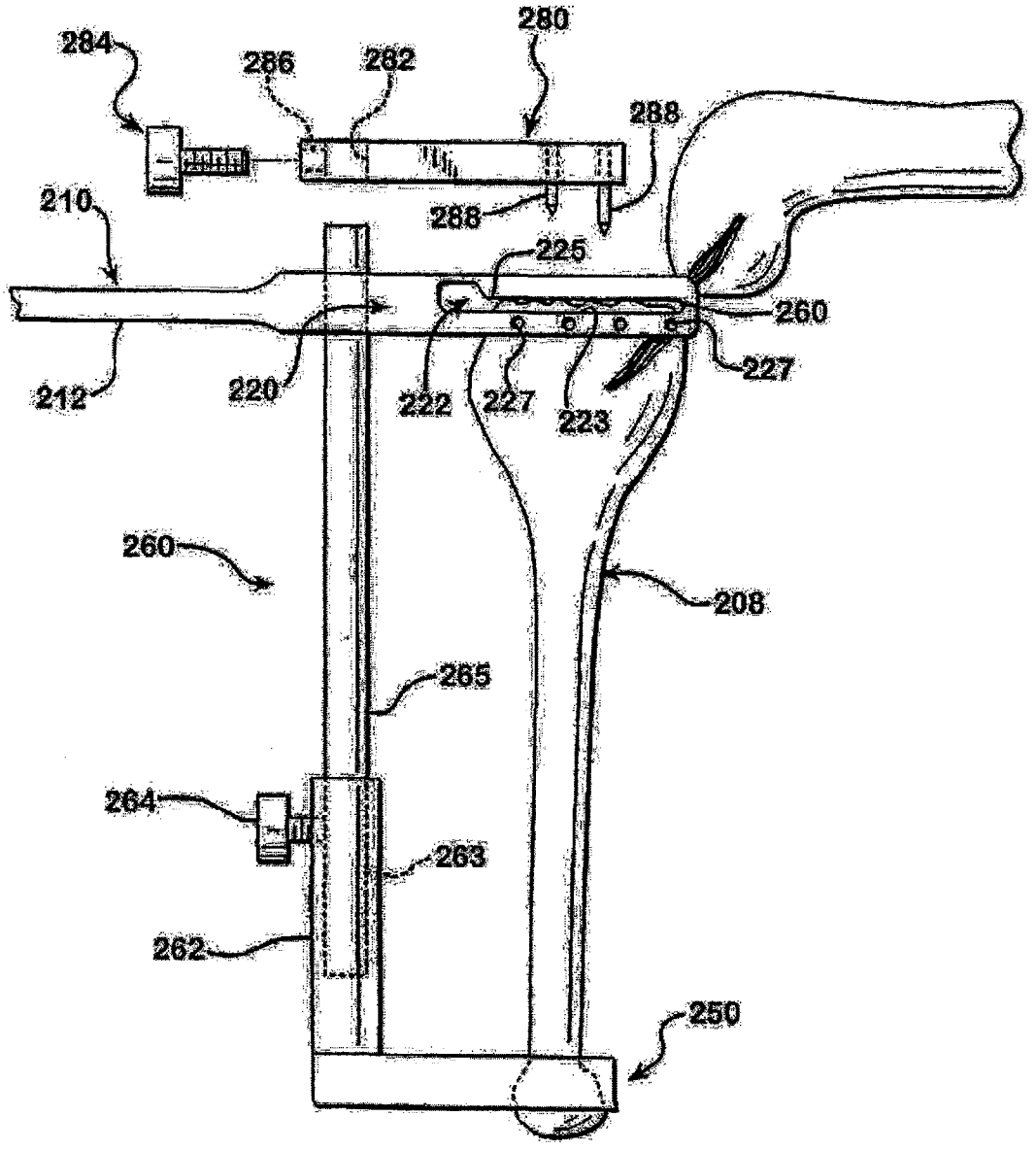
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FIG. 9

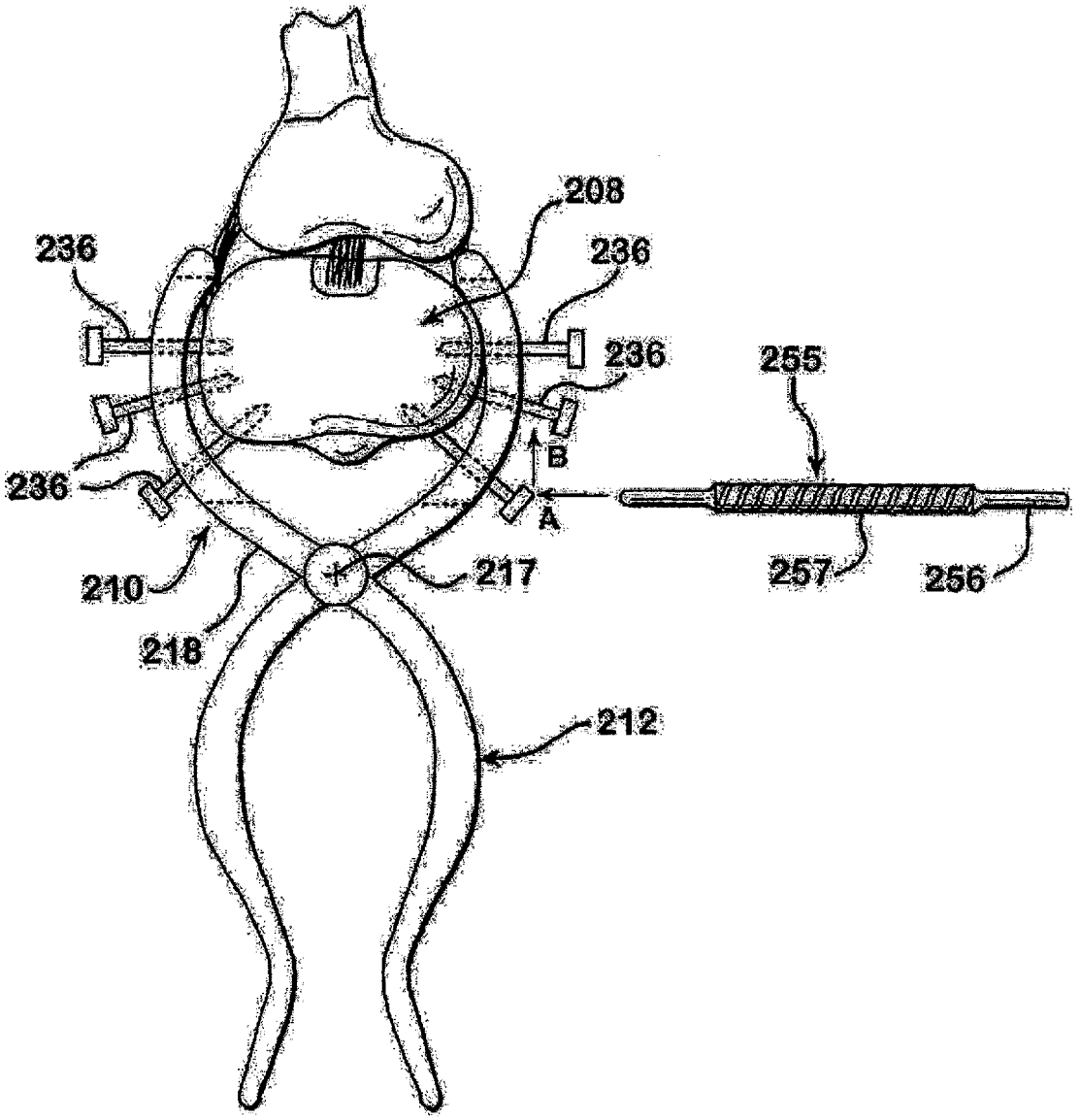
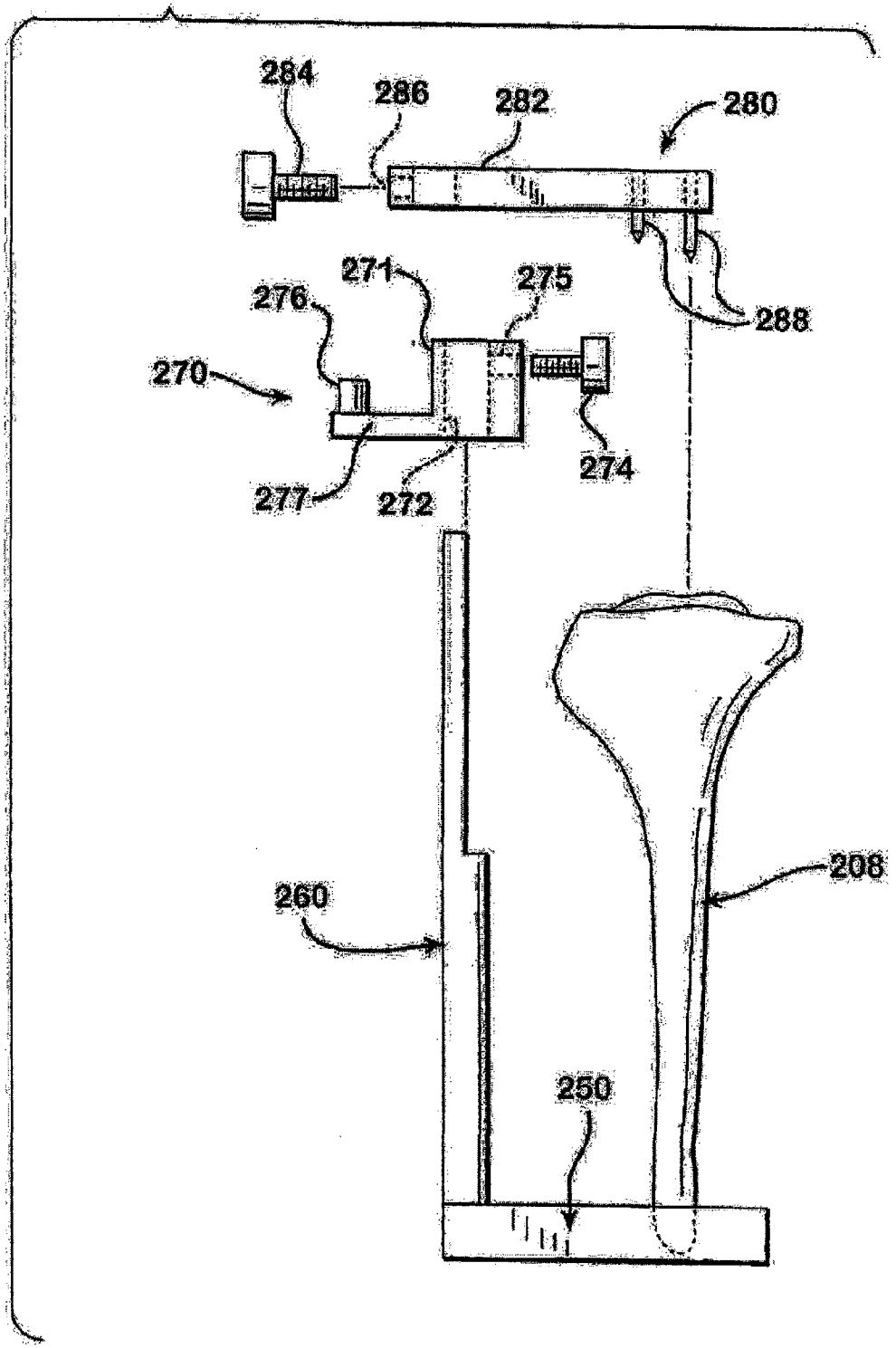


FIG. 10



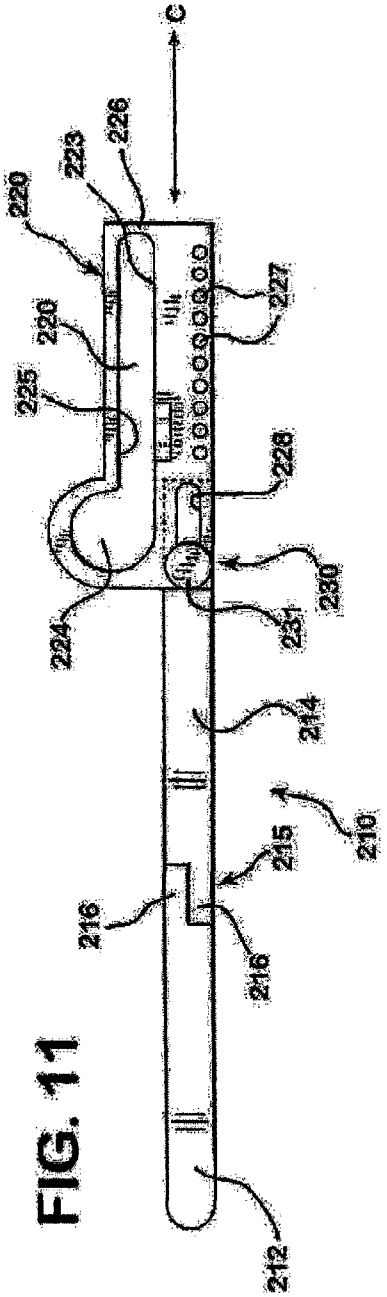

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FIG. 11

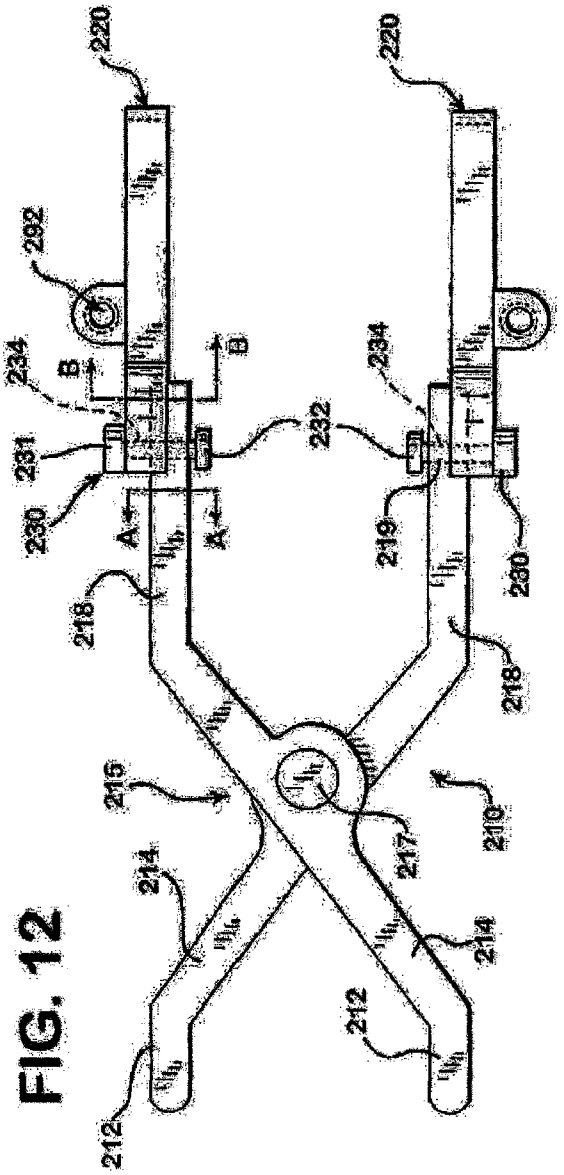
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FIG. 12

FIG. 13

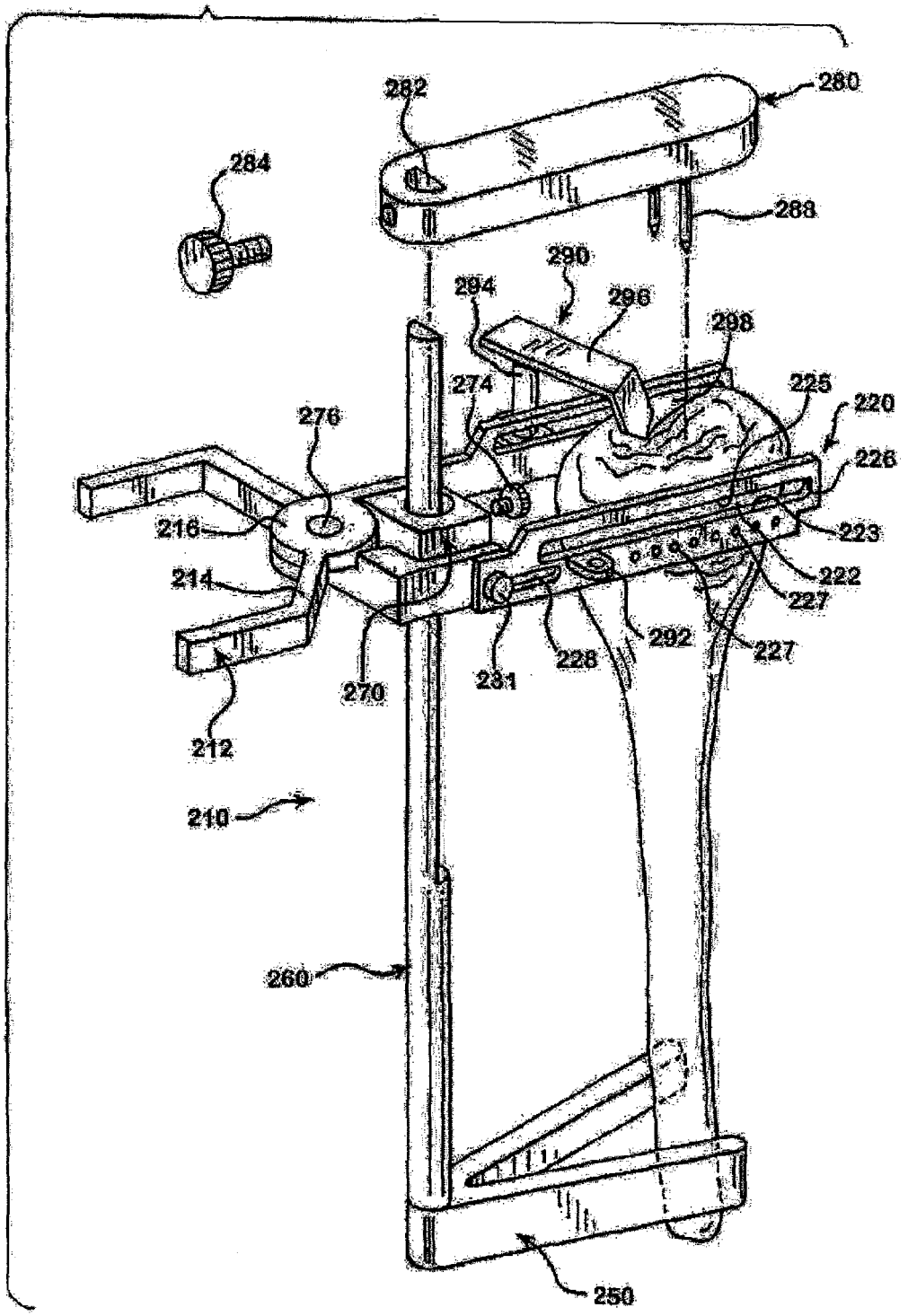
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FIG. 14

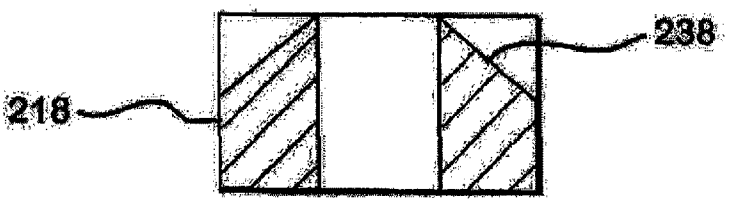


FIG. 15

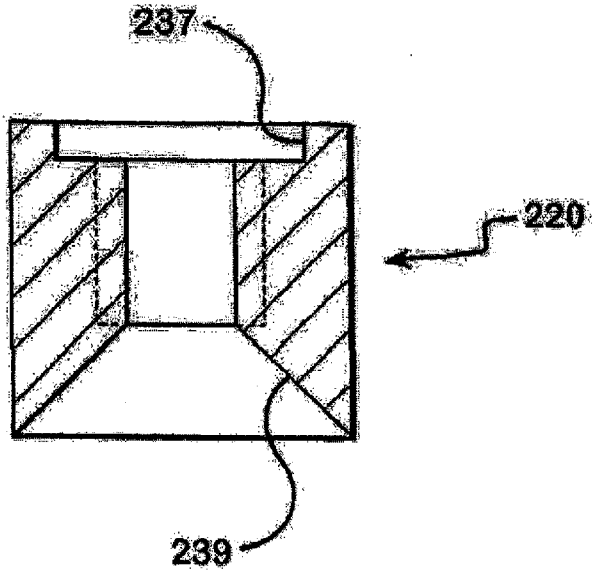


FIG. 16

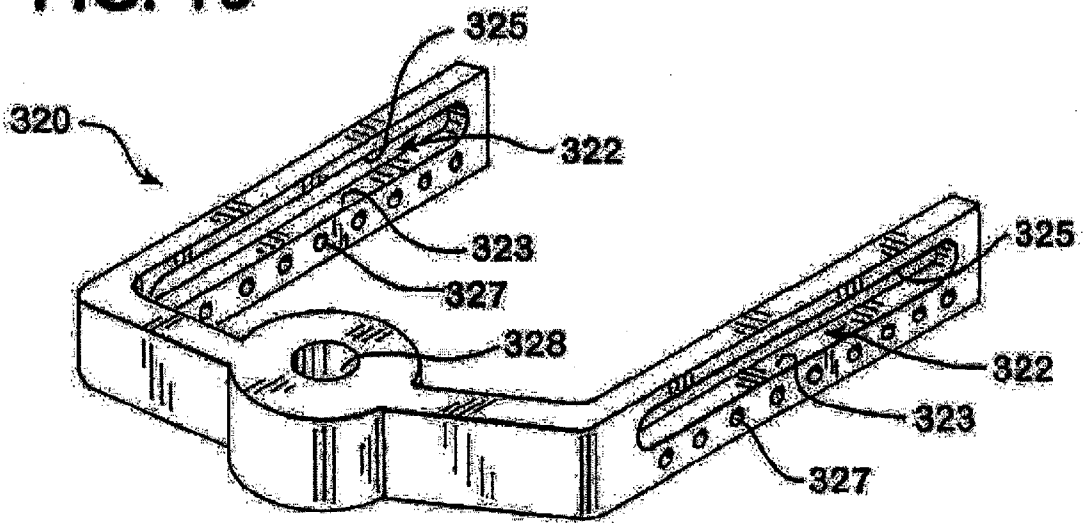
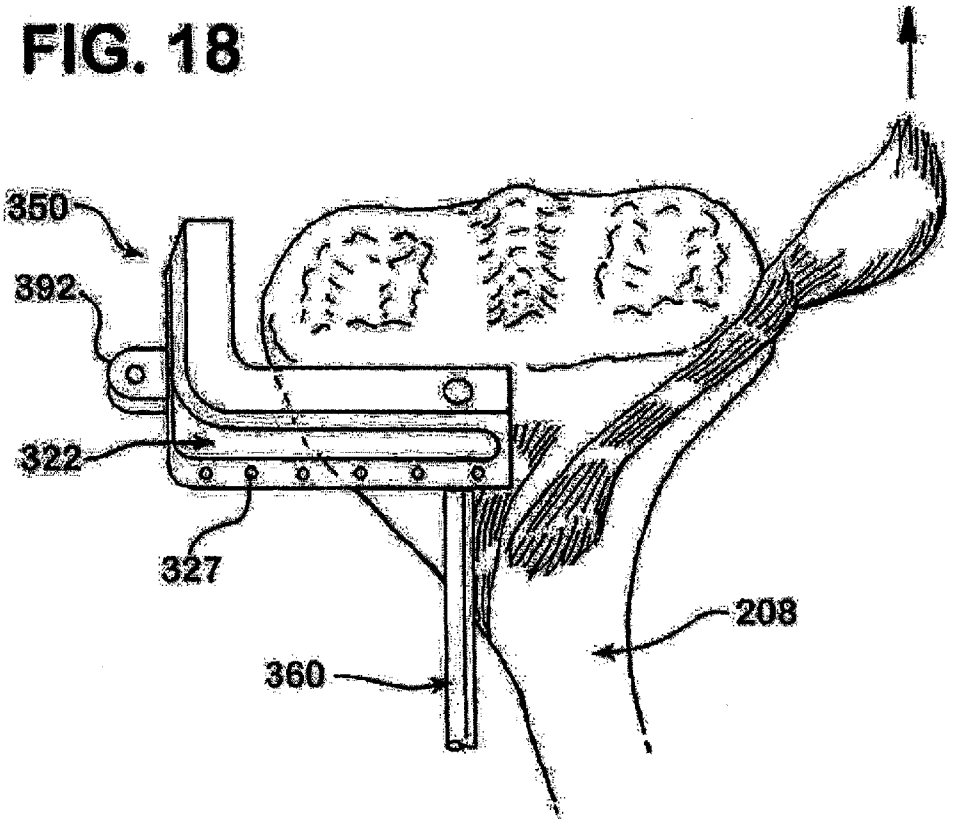


FIG. 18



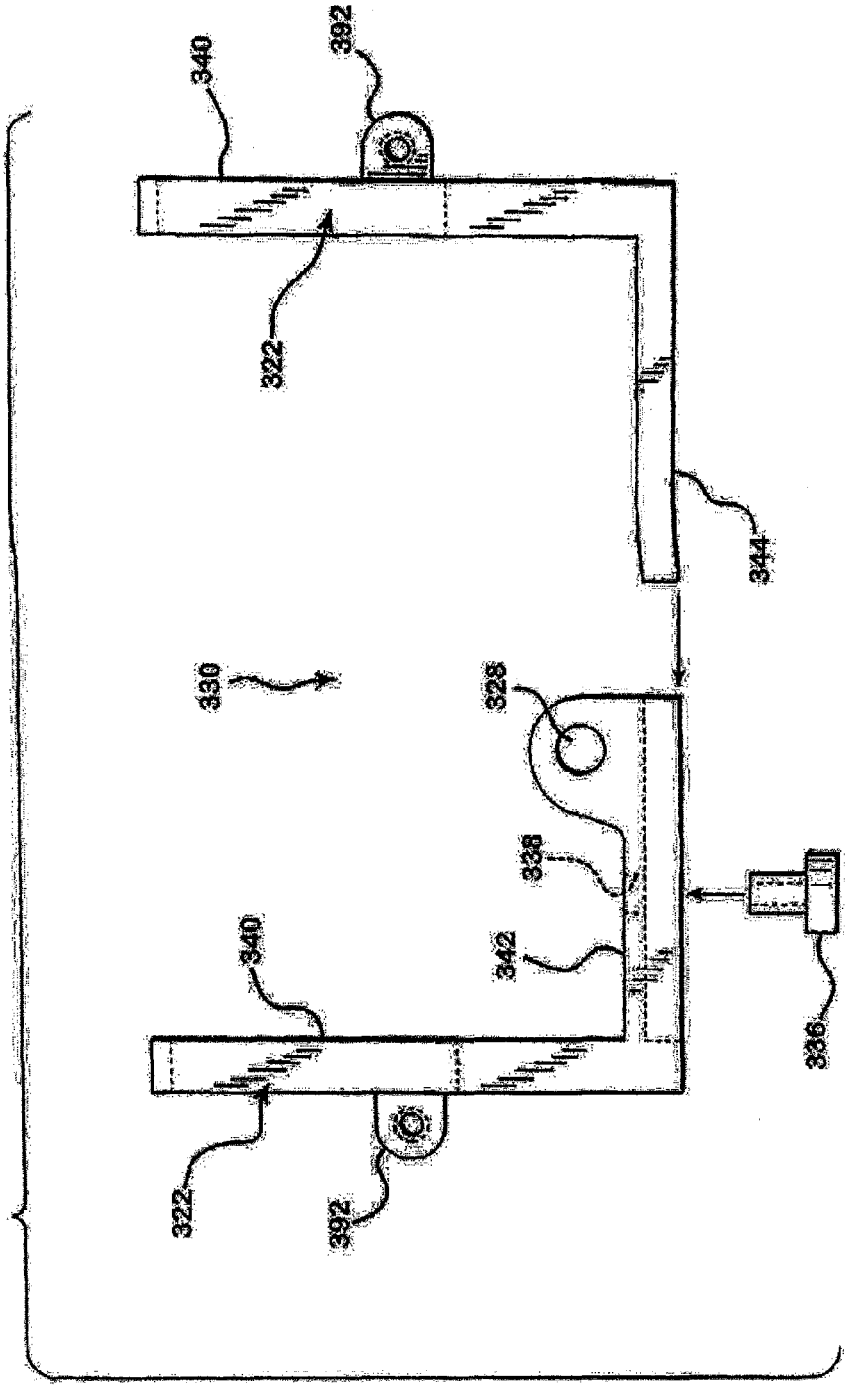


FIG. 17

FIG. 19

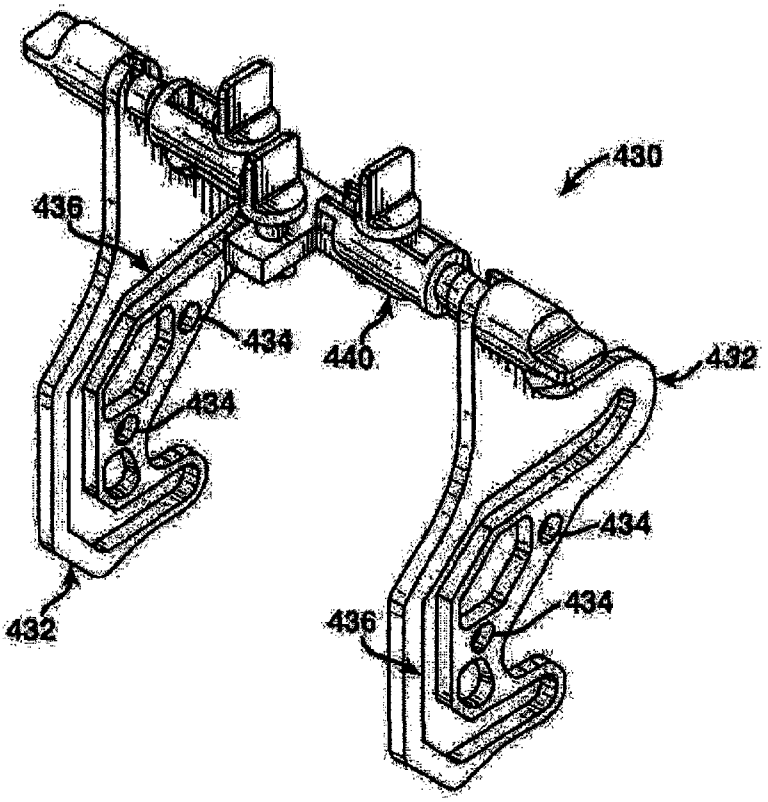

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FIG. 20

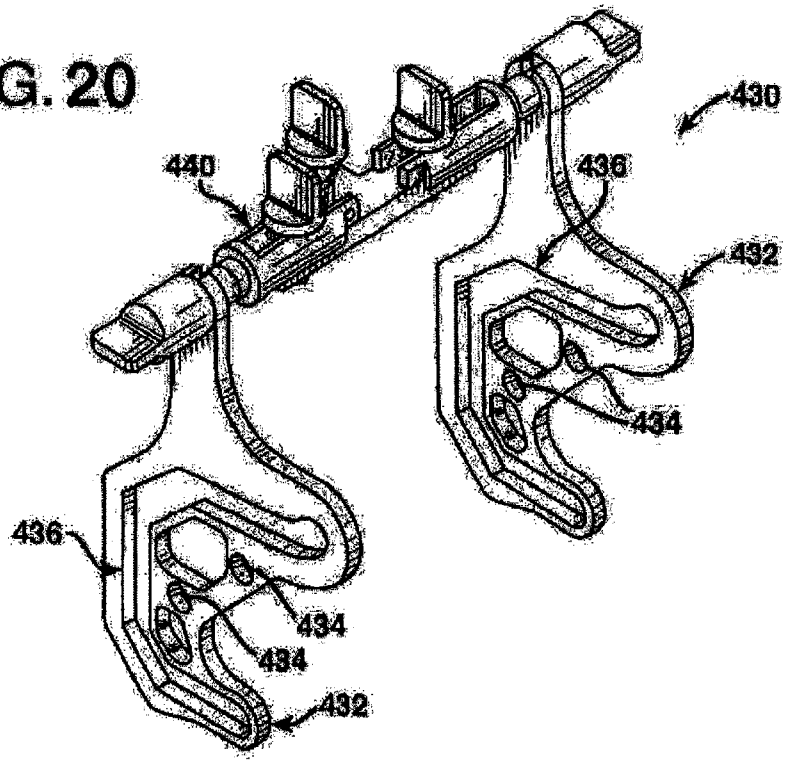
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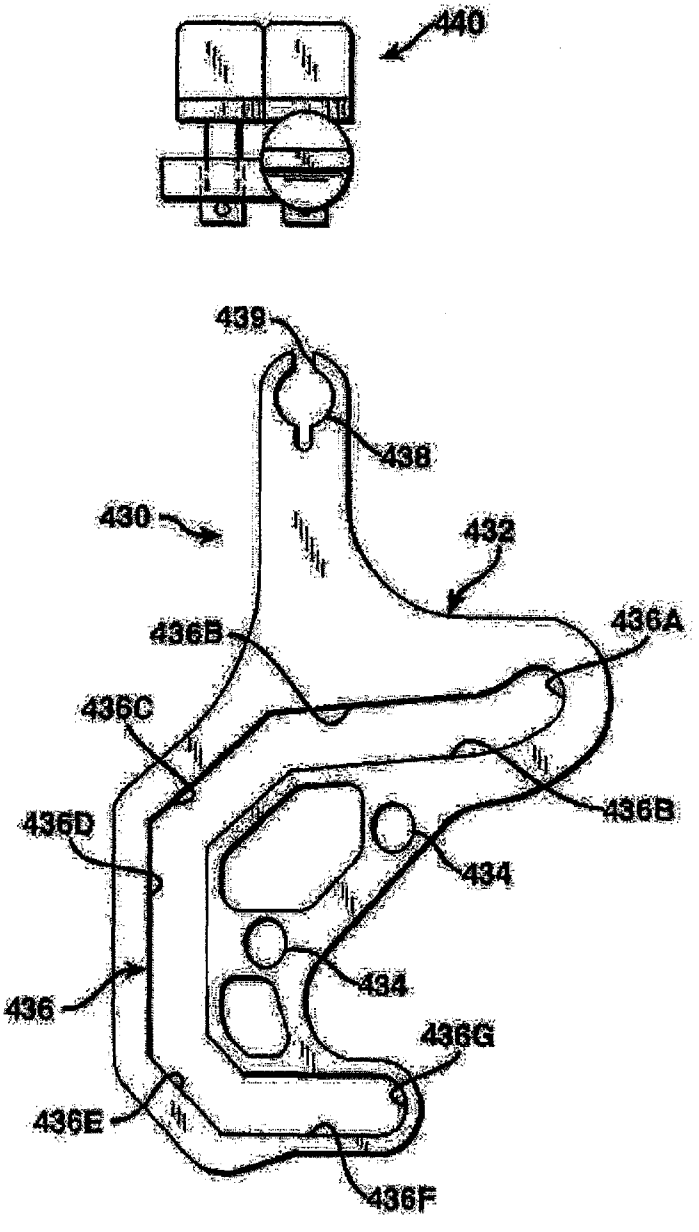
FIG. 21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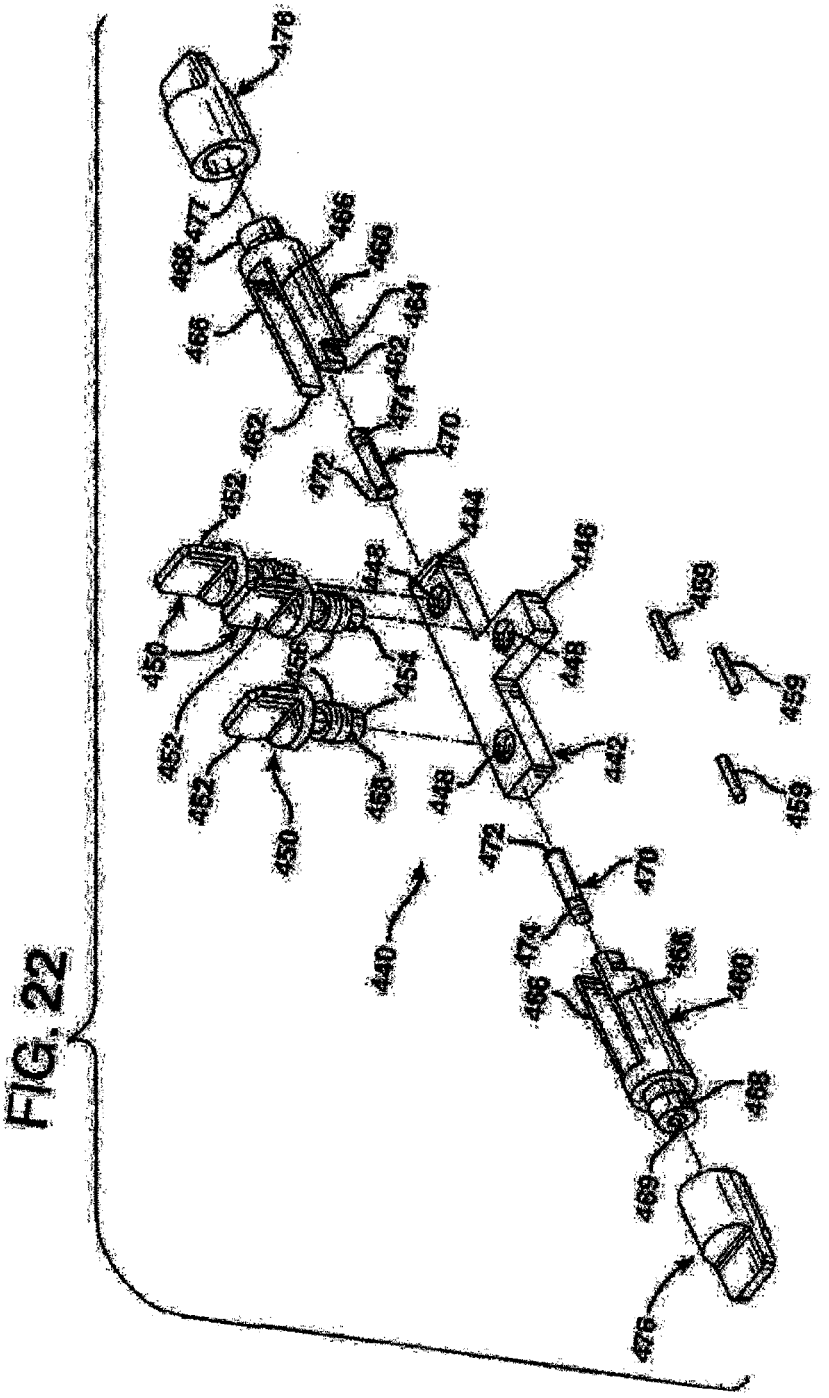
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FIG. 22

FIG. 23

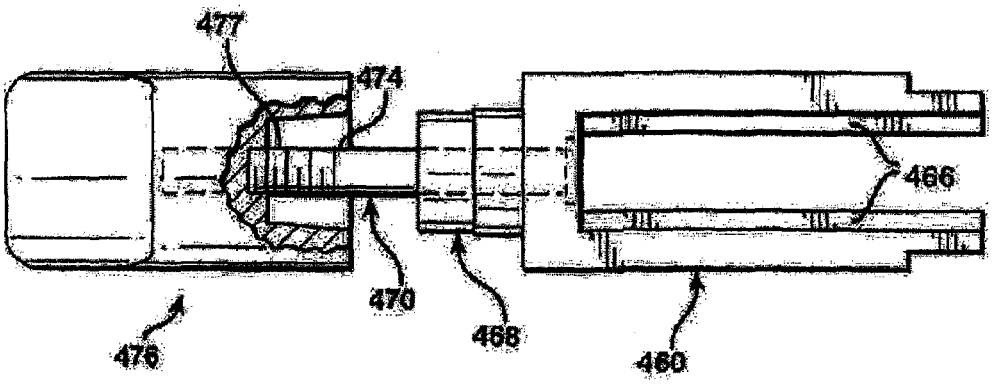
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FIG. 24

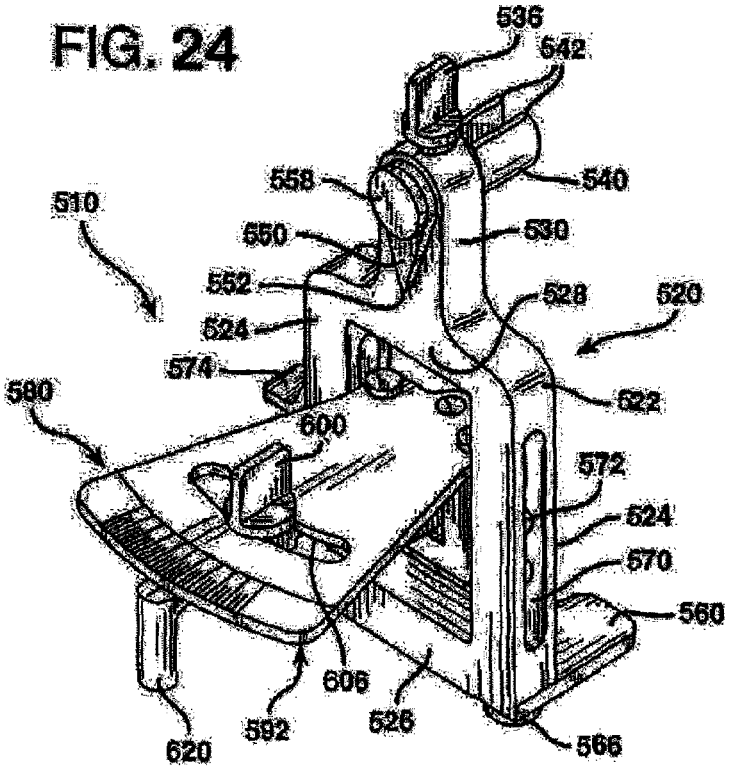
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FIG. 25

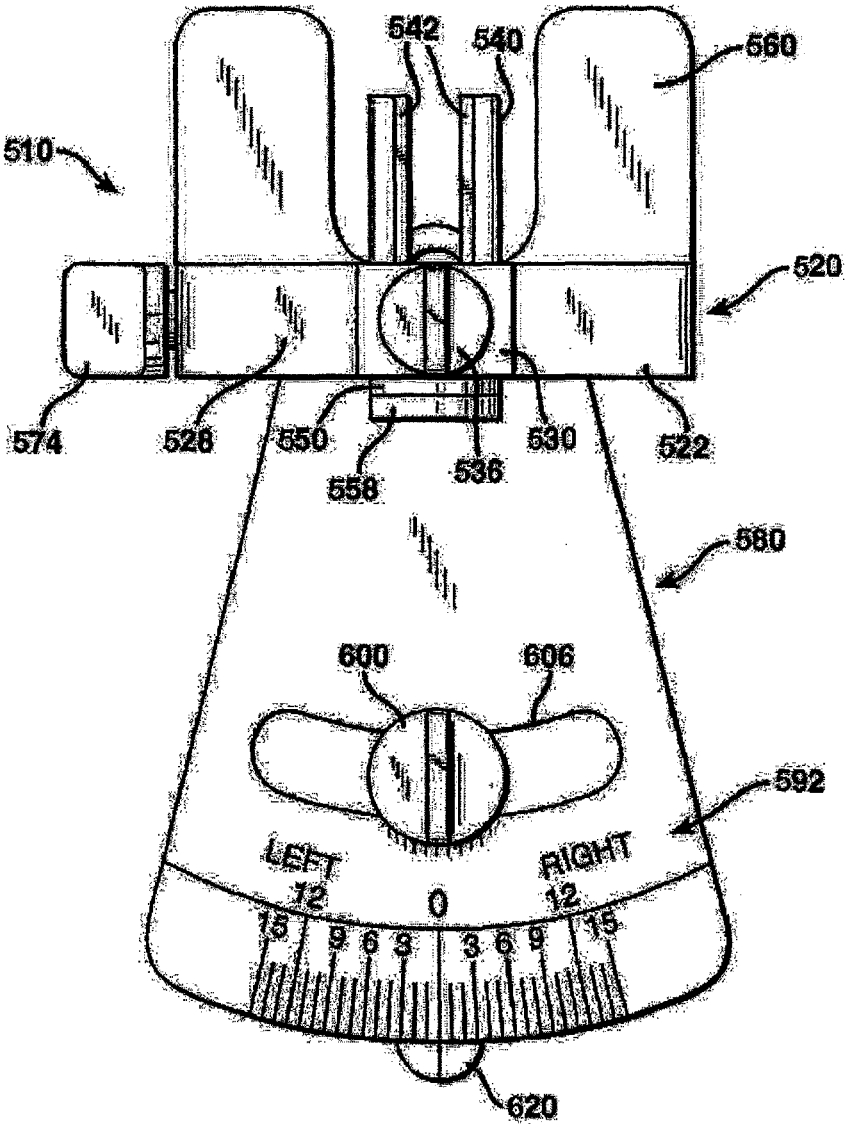
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FIG. 26

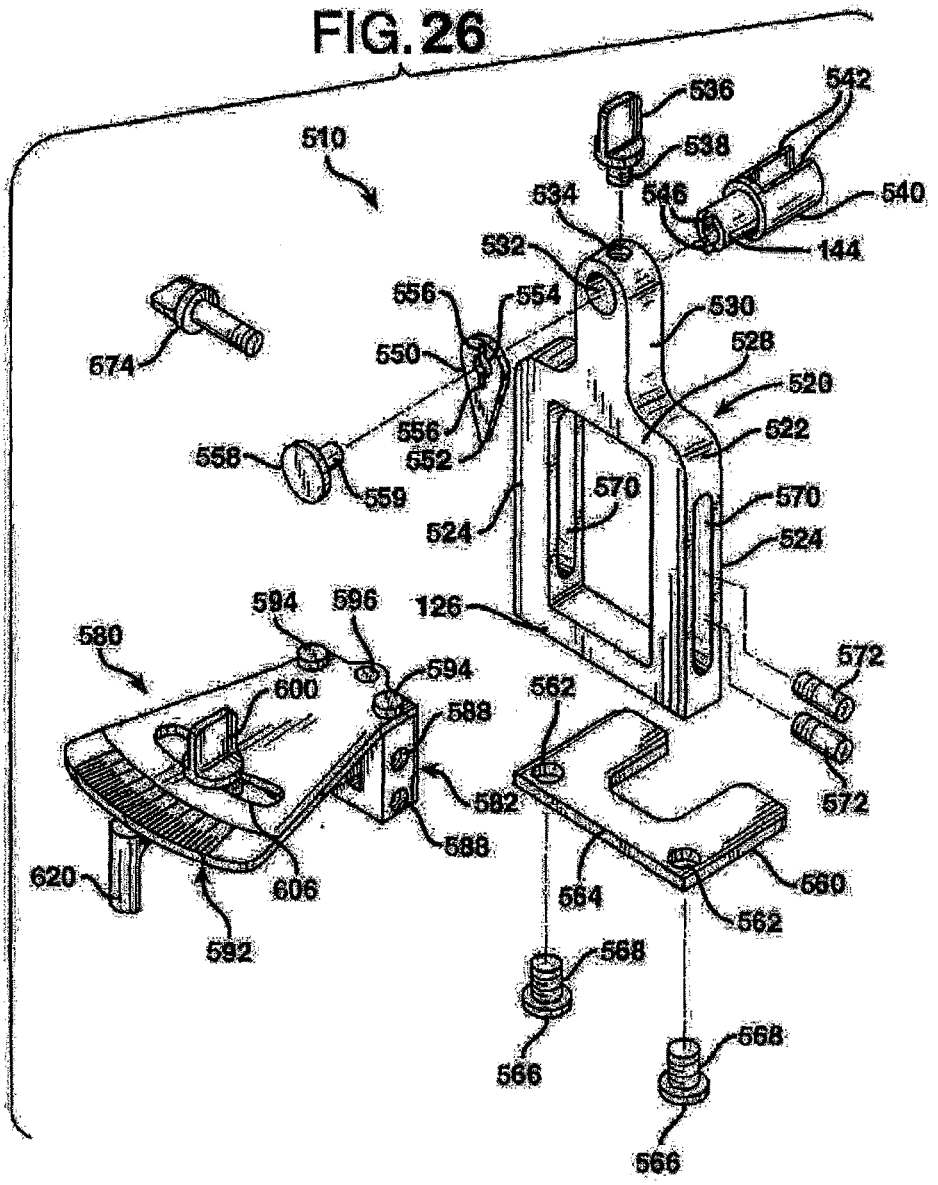
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FIG.27

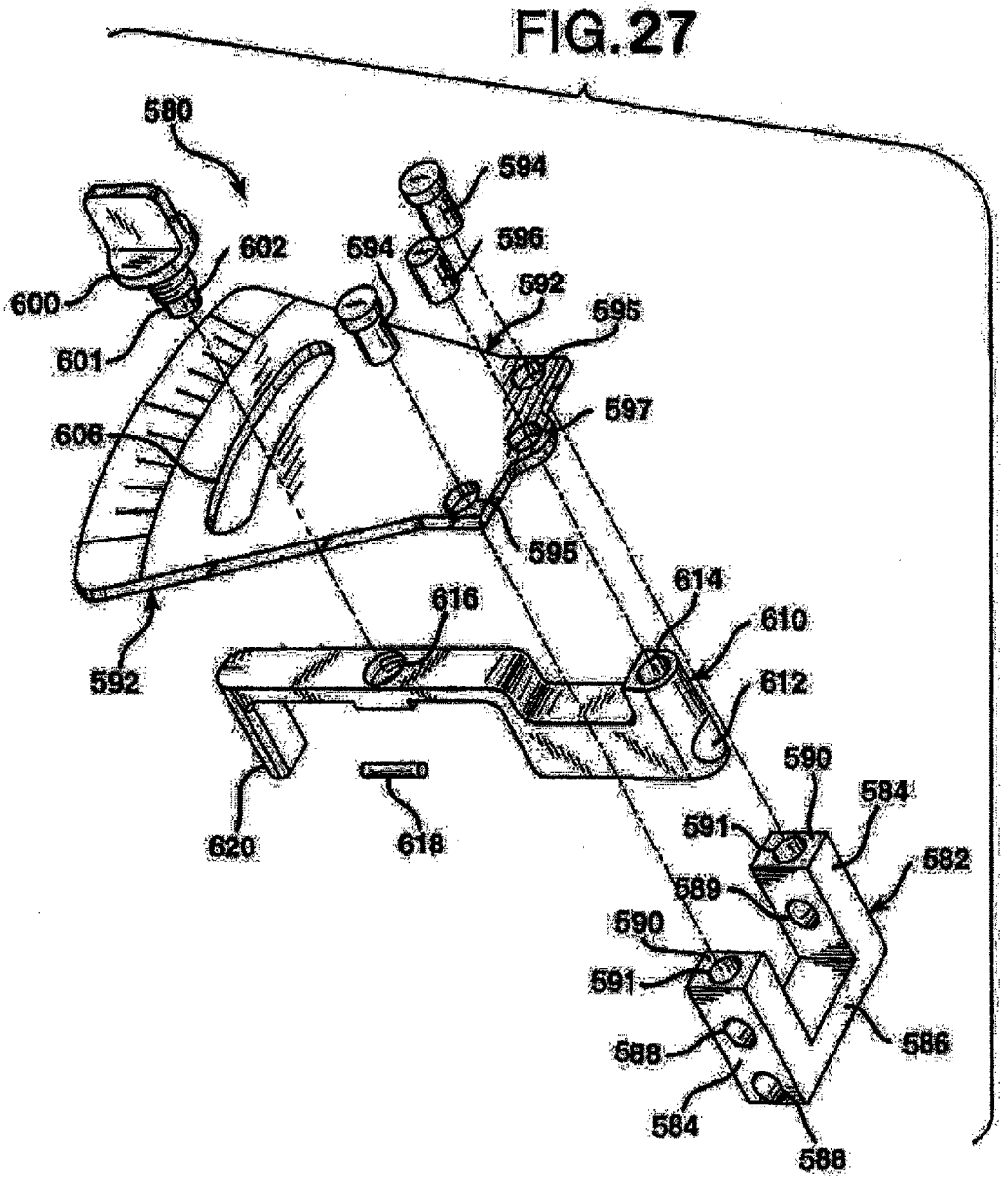
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FIG. 28A

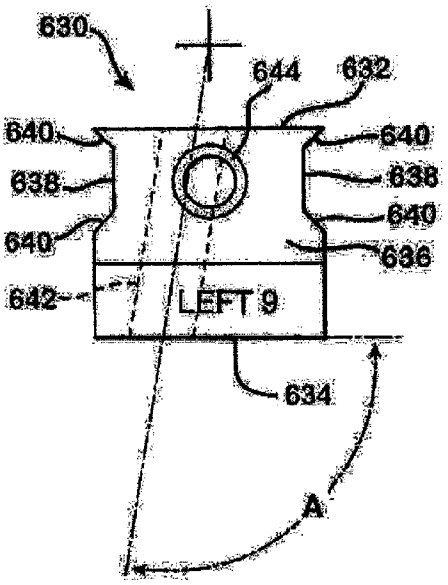

FIG. 28B

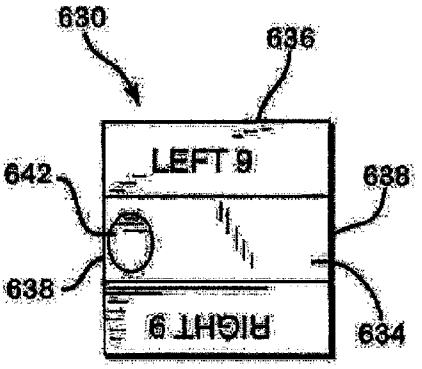

FIG. 28C

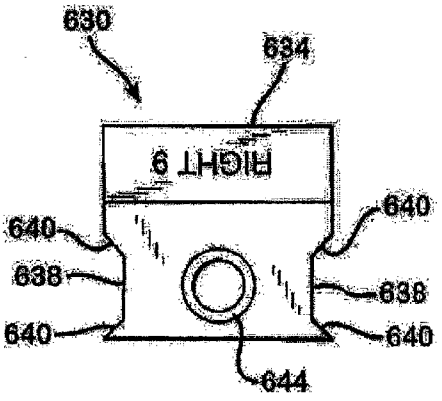

FIG. 28D

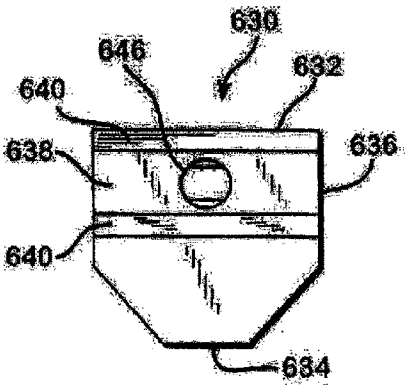

FIG. 29

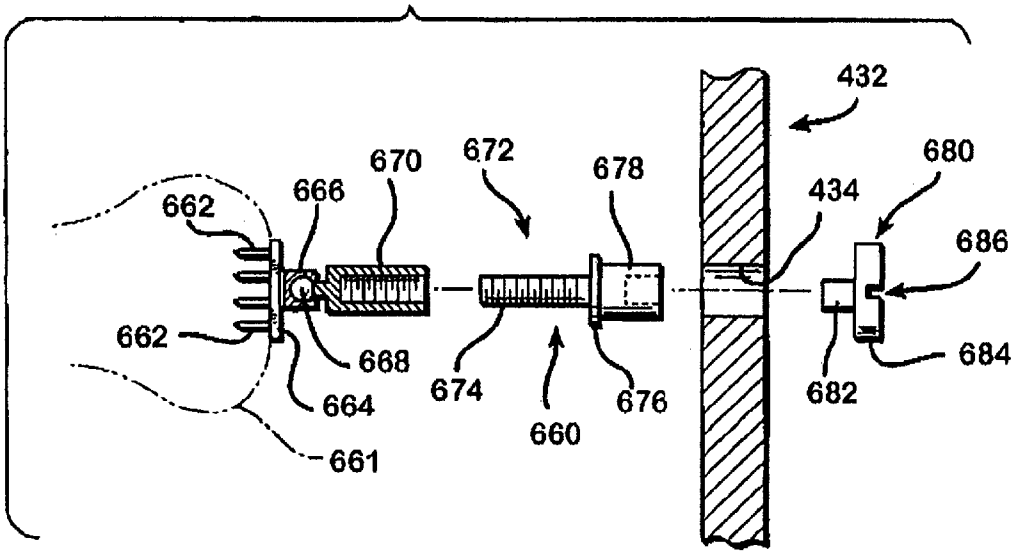
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FIG. 30

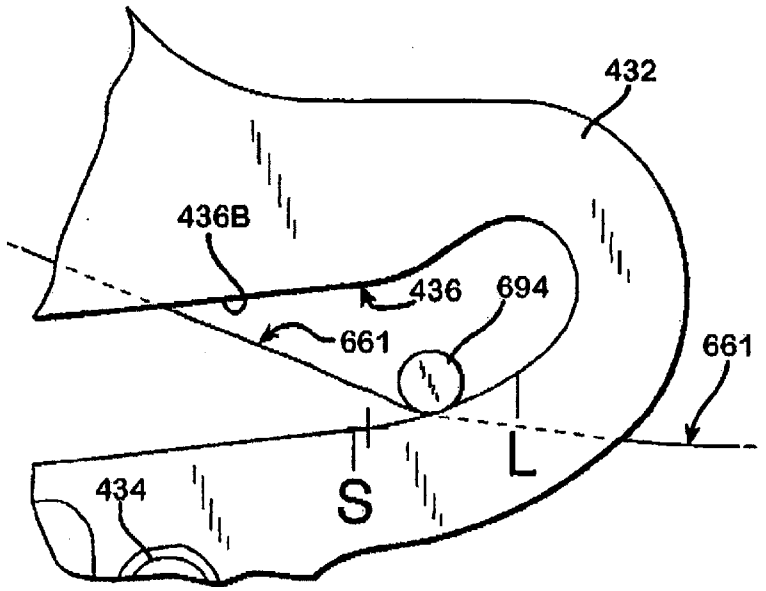
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FIG. 31

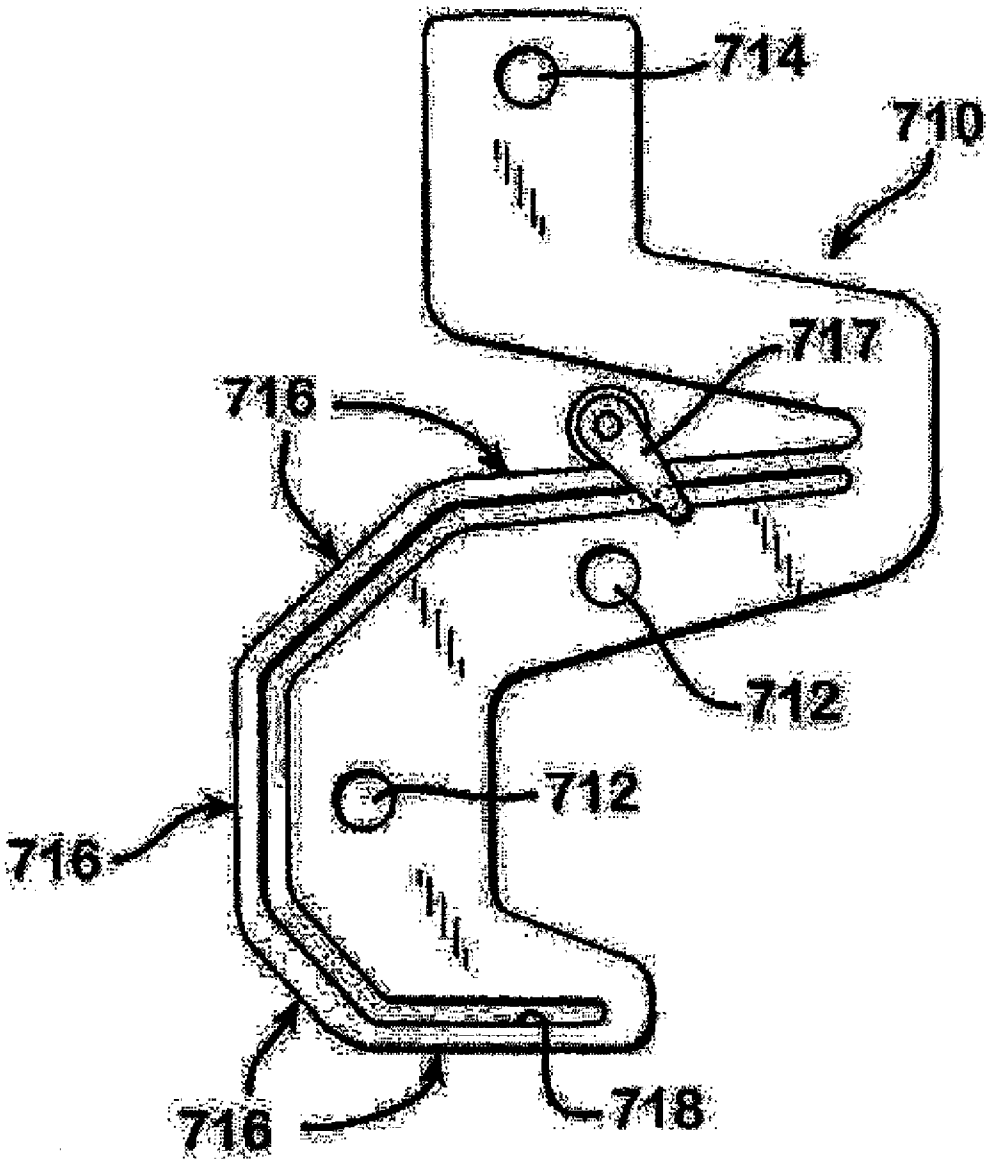


FIG.32

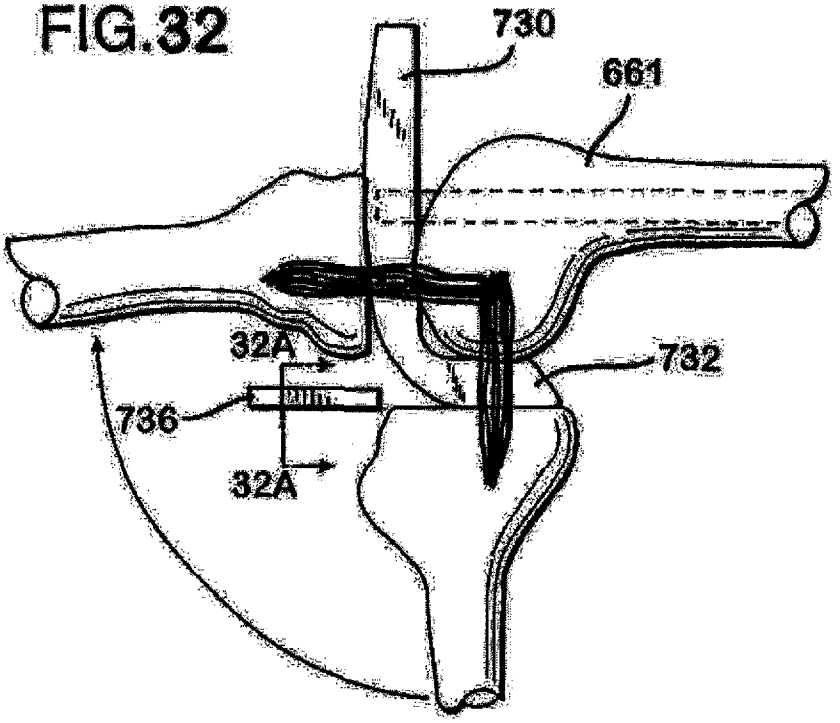


FIG.32A

FIG.32B

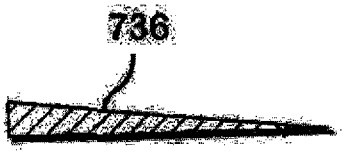
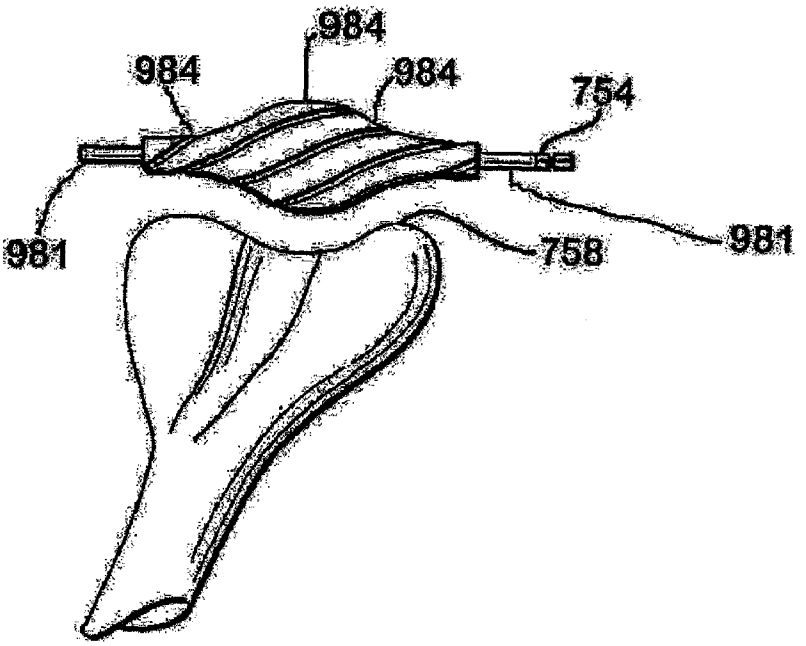


FIG. 33A

FIG. 33B



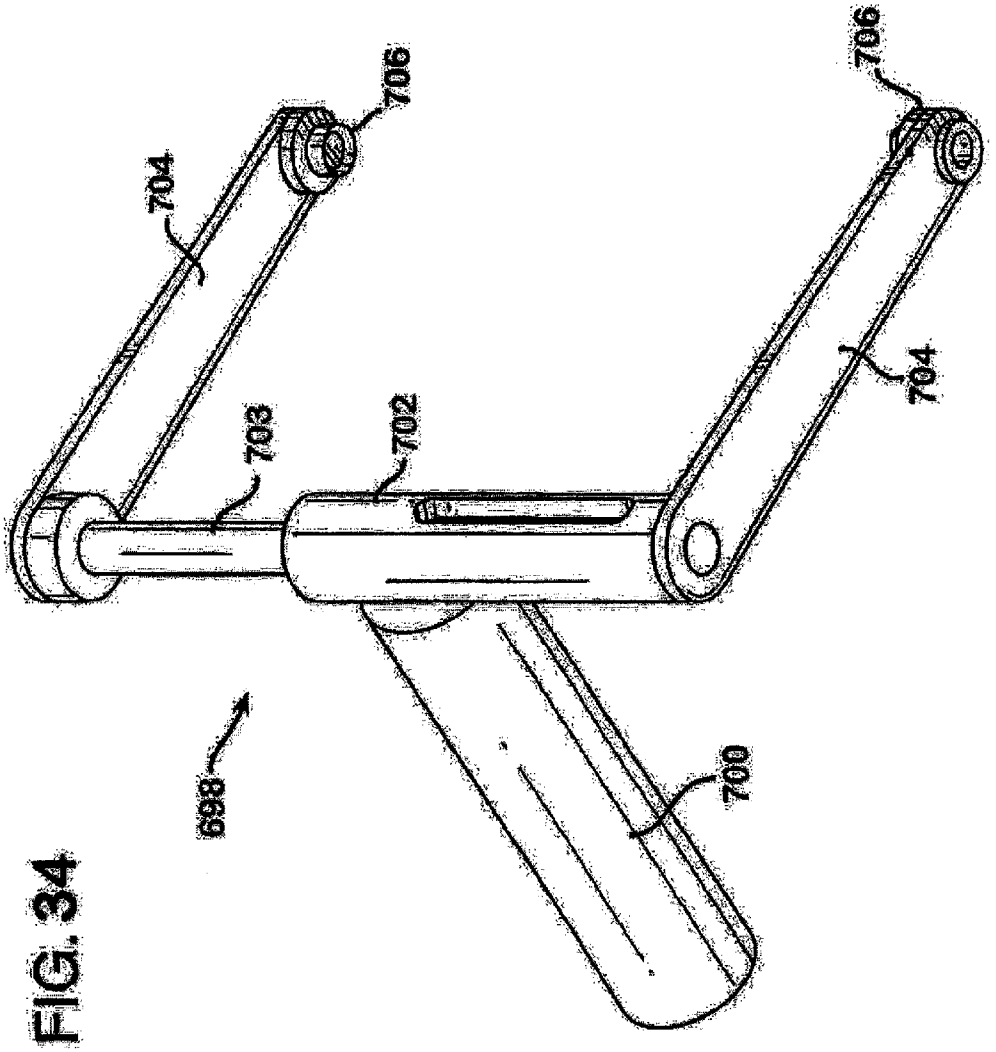
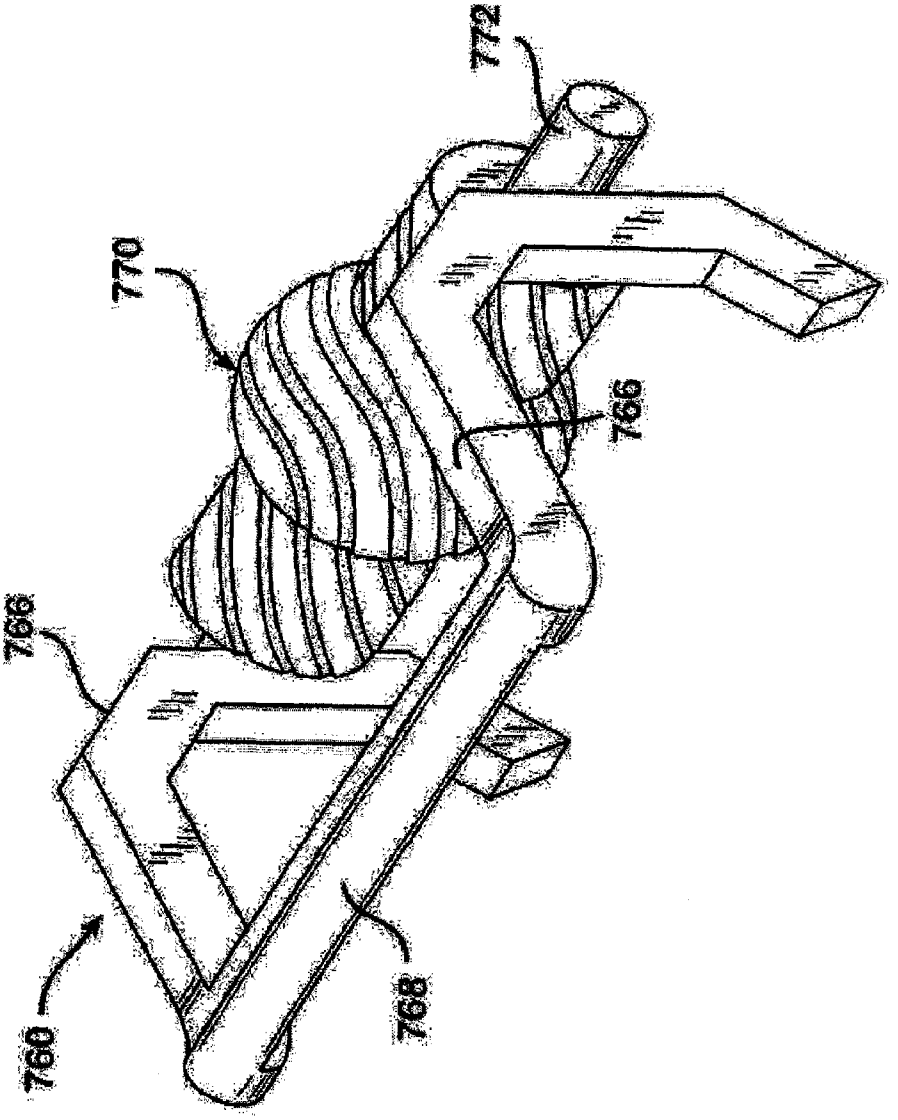


FIG. 34

FIG. 35



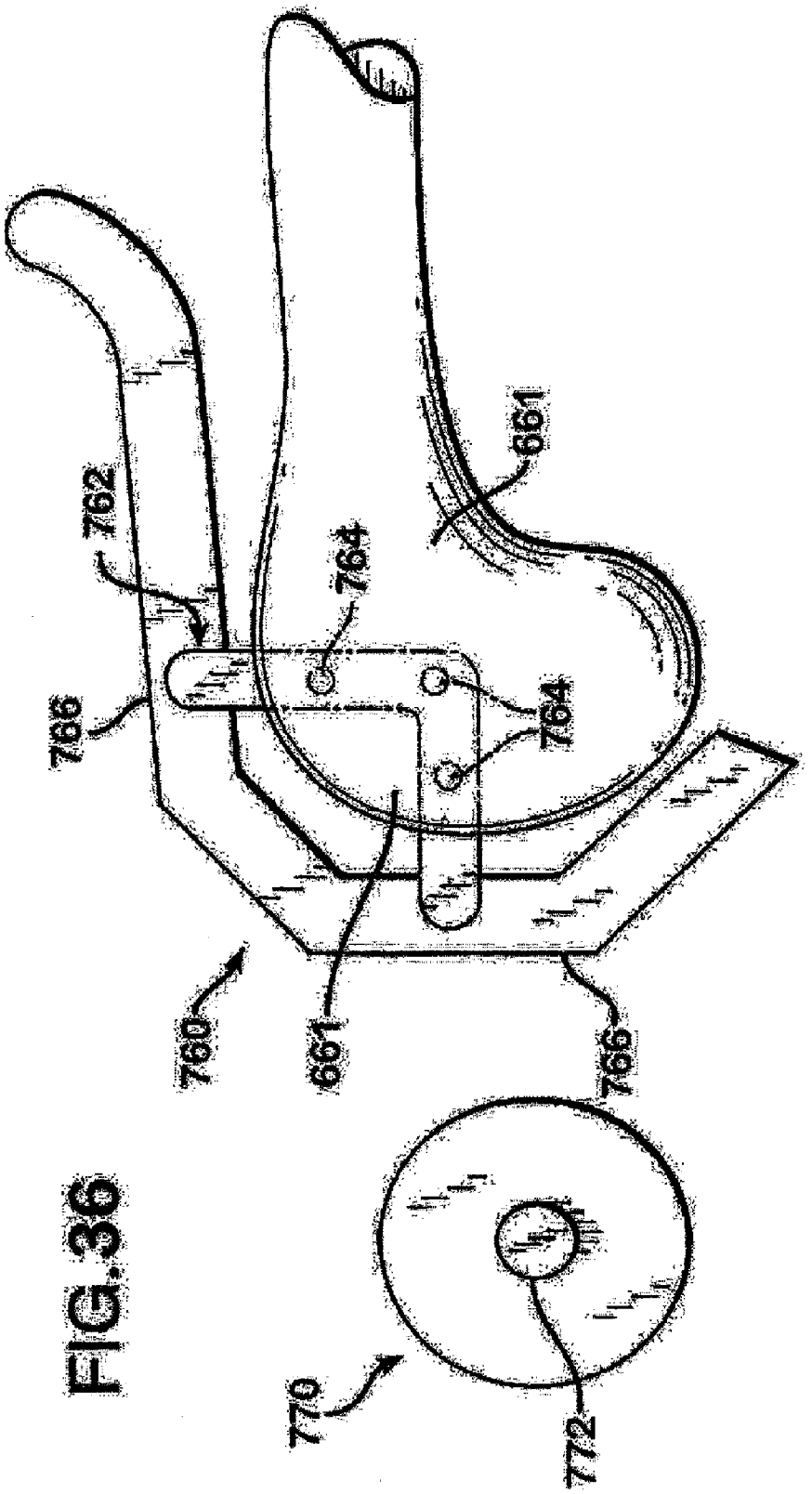


FIG.36

FIG. 37

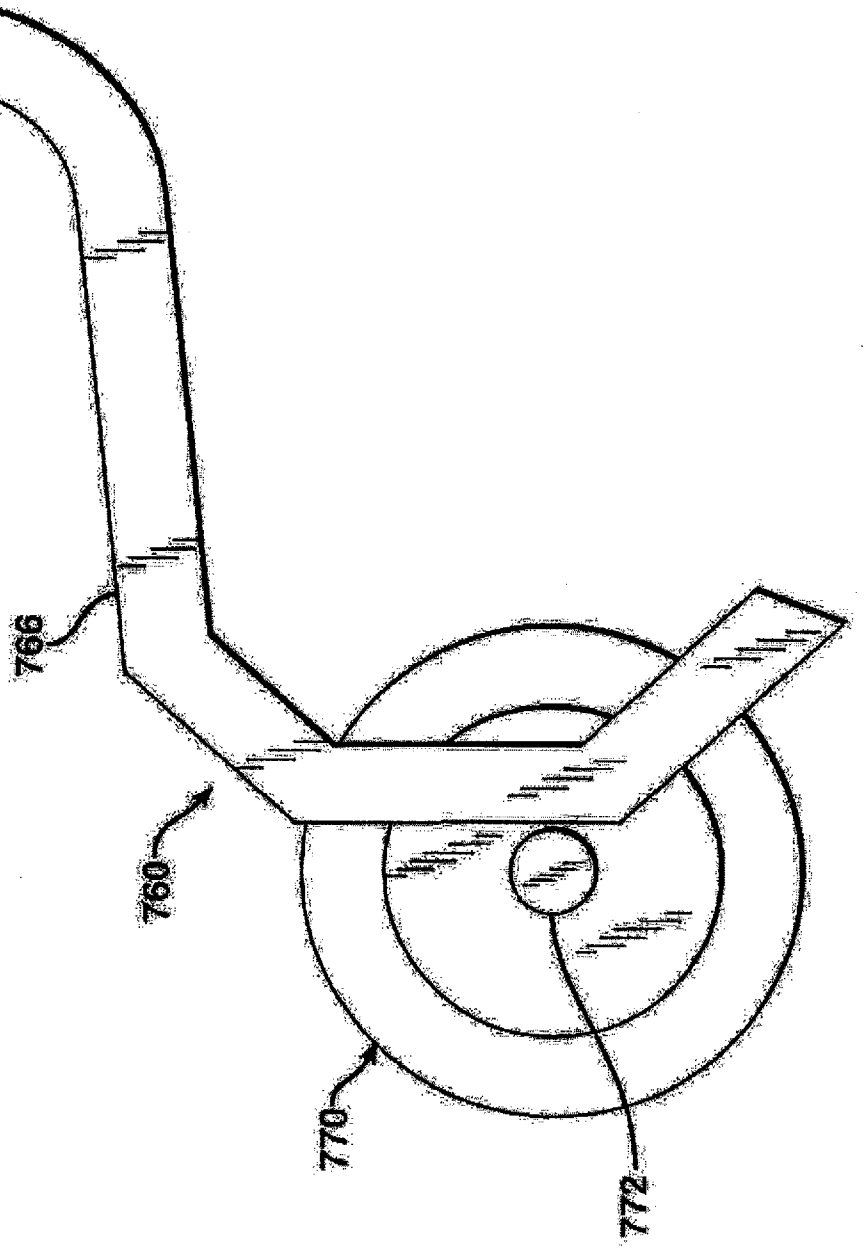


FIG.38

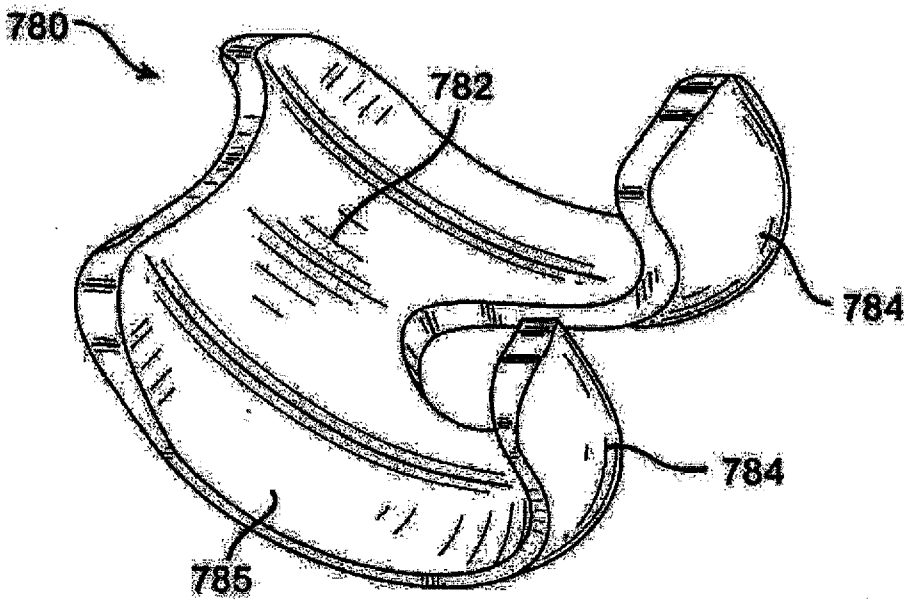
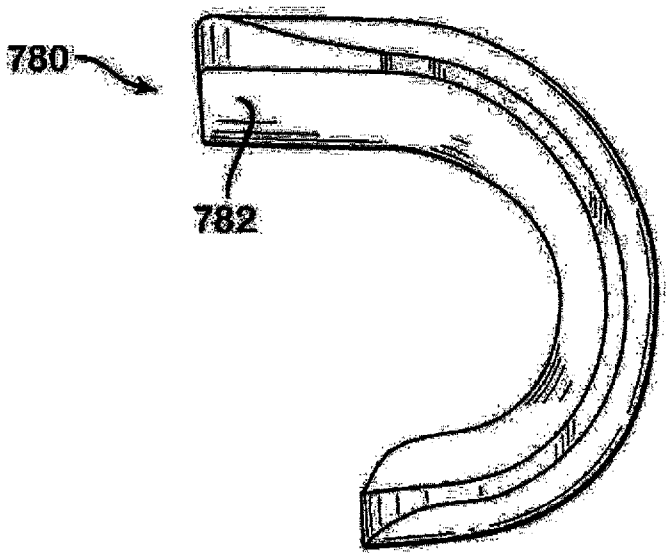


FIG.39



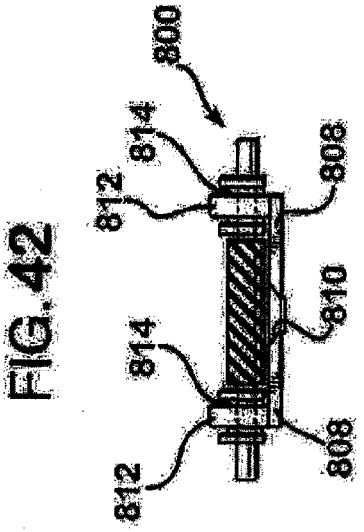


FIG. 42

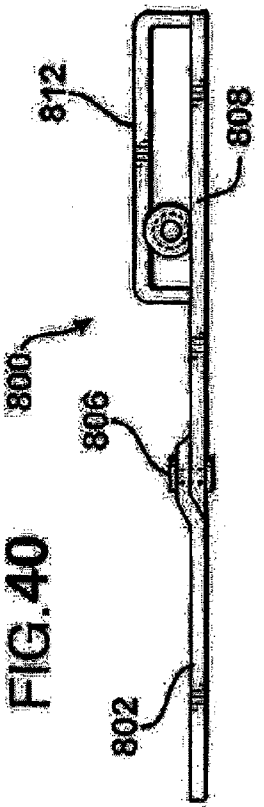


FIG. 40

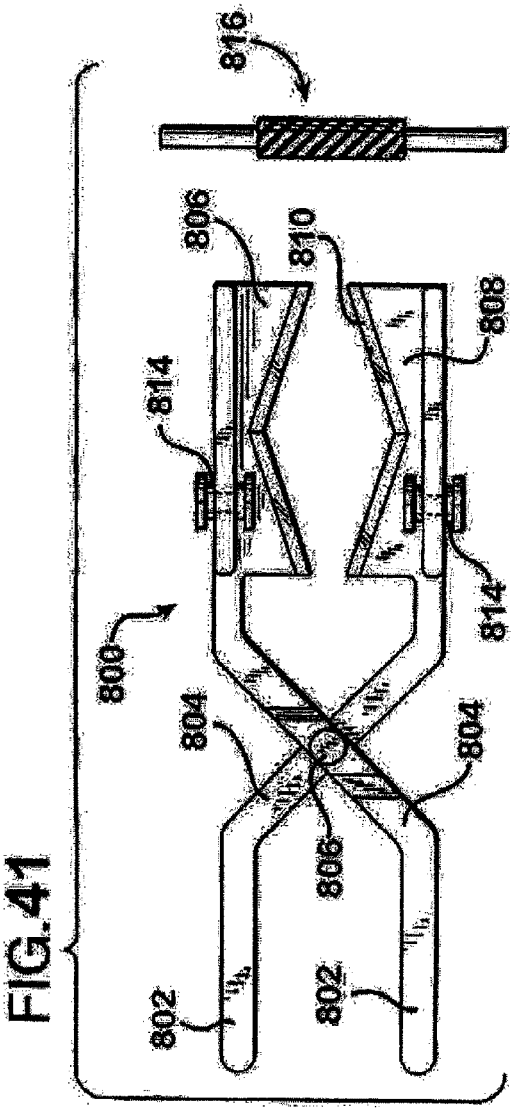


FIG. 41

FIG. 43

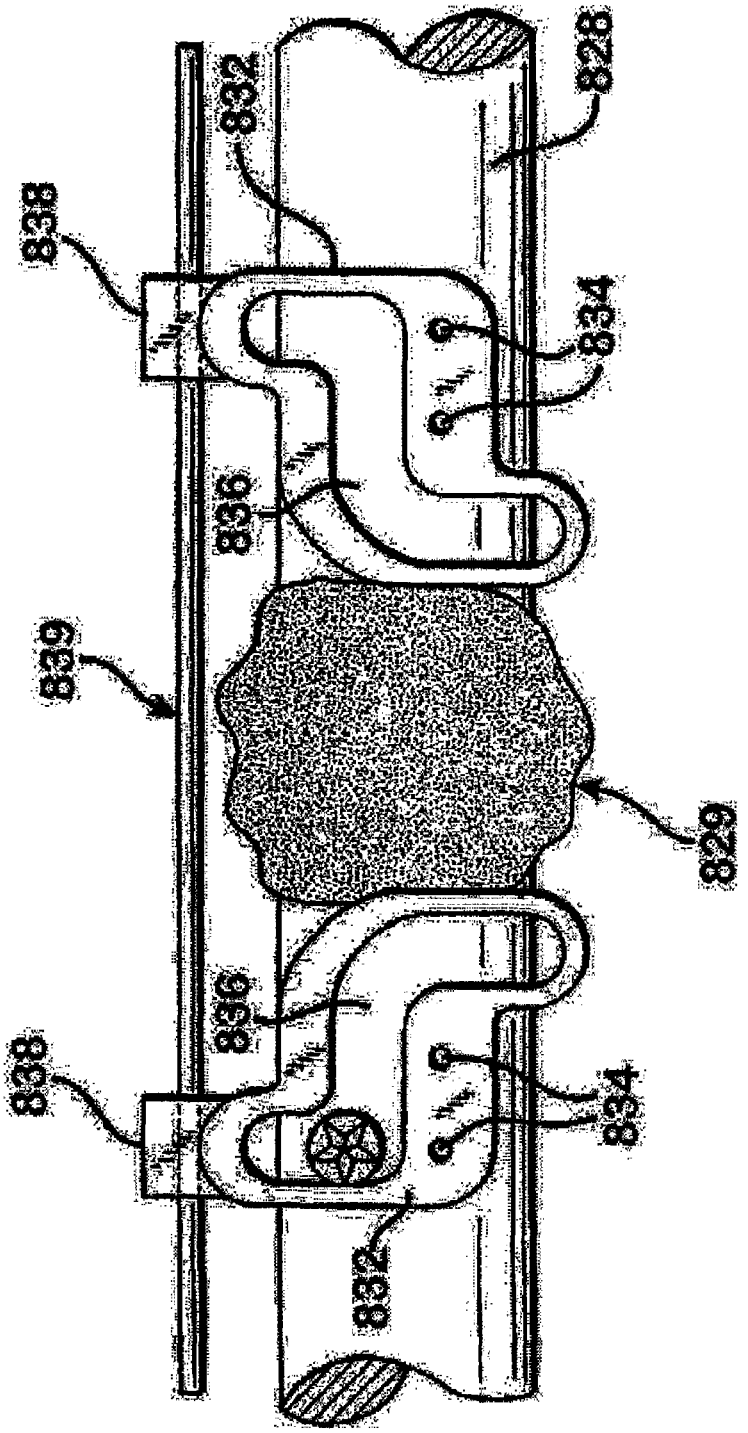


FIG.44

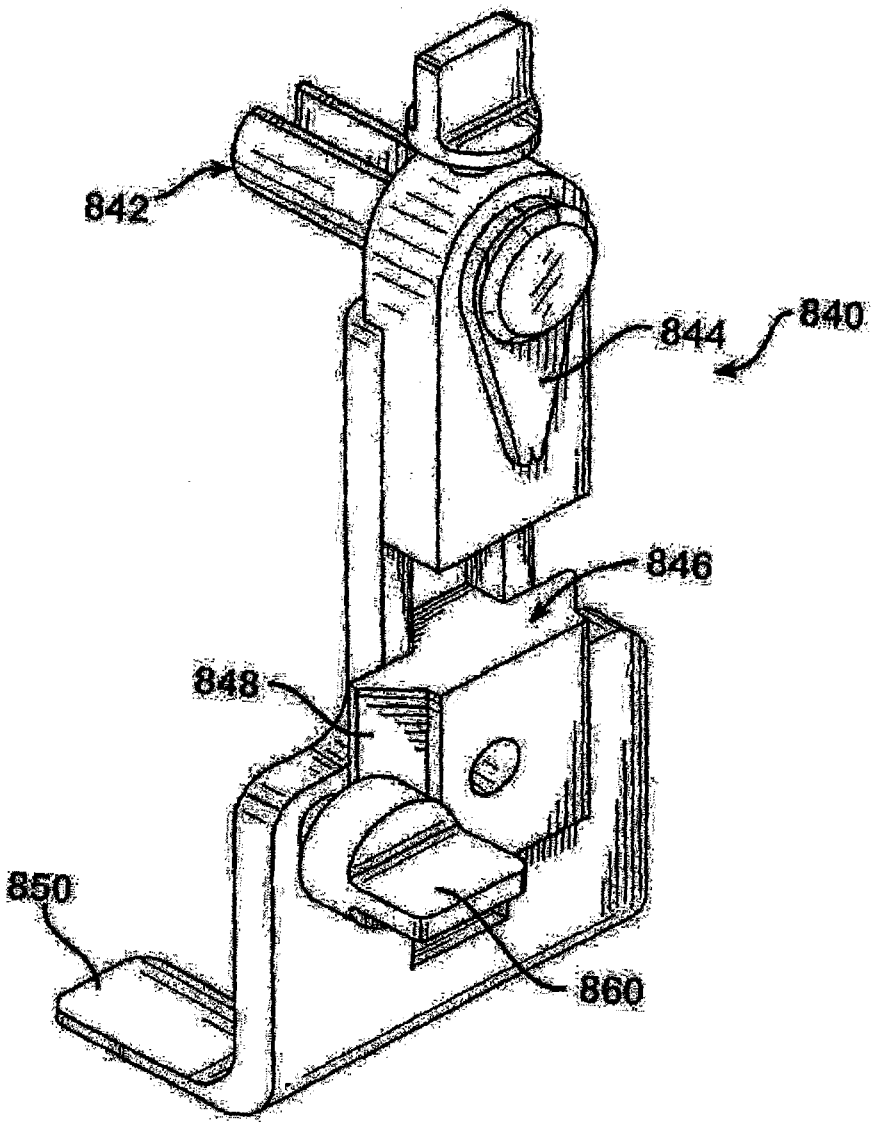


FIG. 45

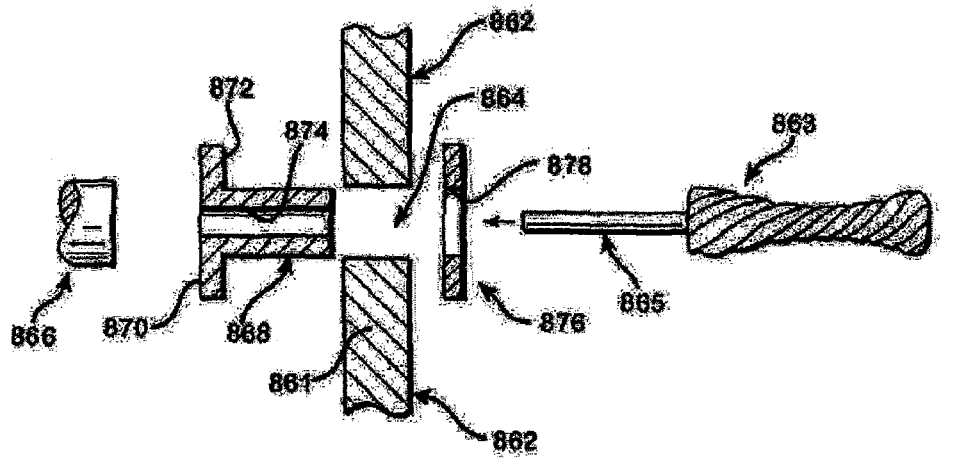

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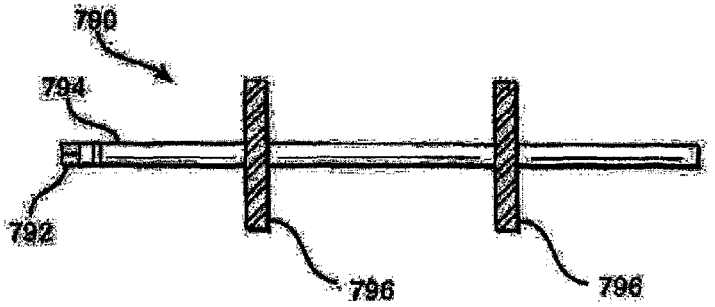
FIG. 47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796
796

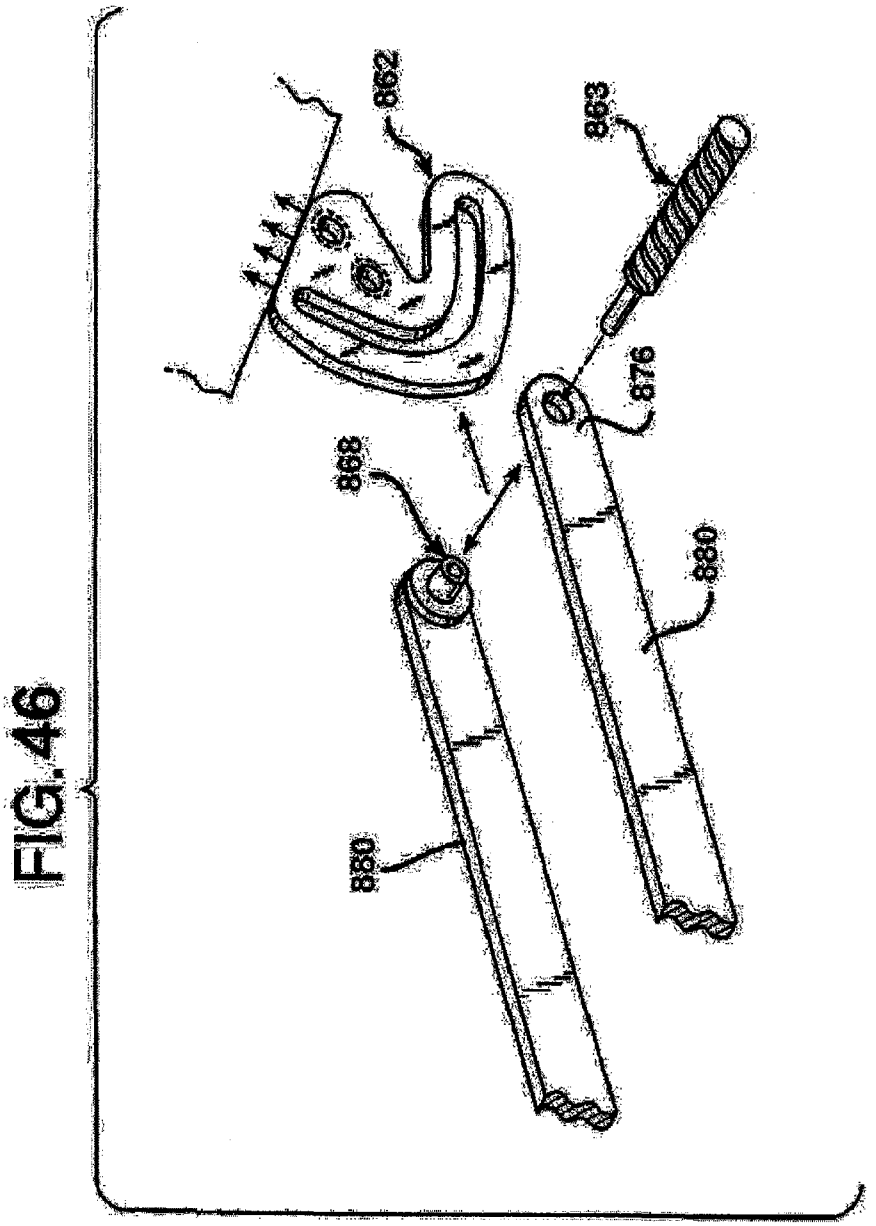


FIG. 46

FIG. 48

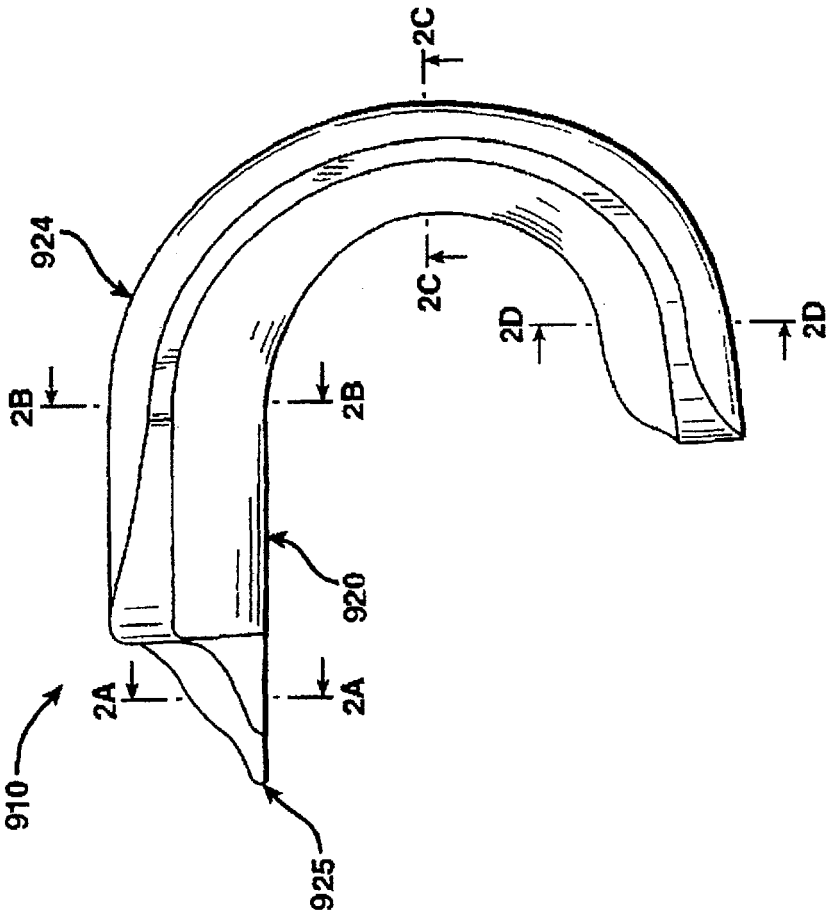


FIG. 48A

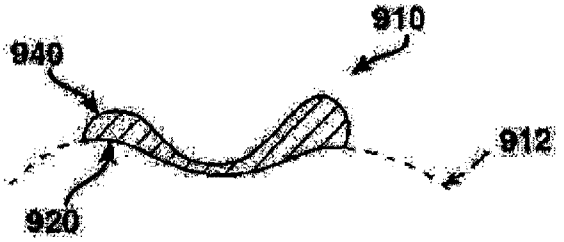


FIG. 48B

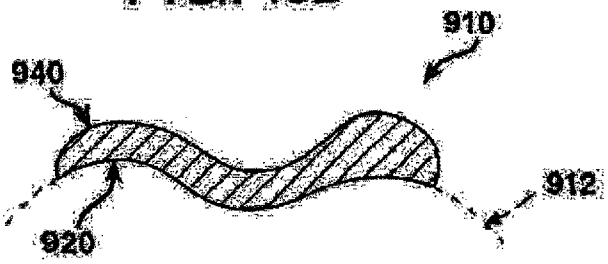


FIG. 48C

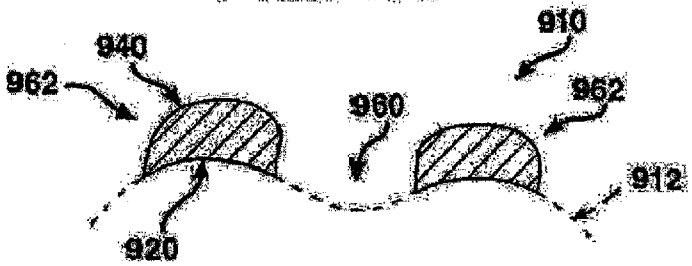


FIG. 48D

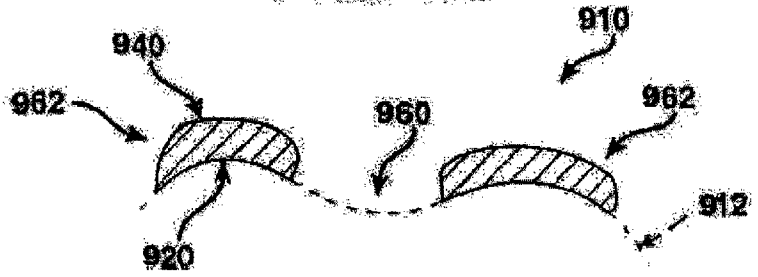


FIG. 49

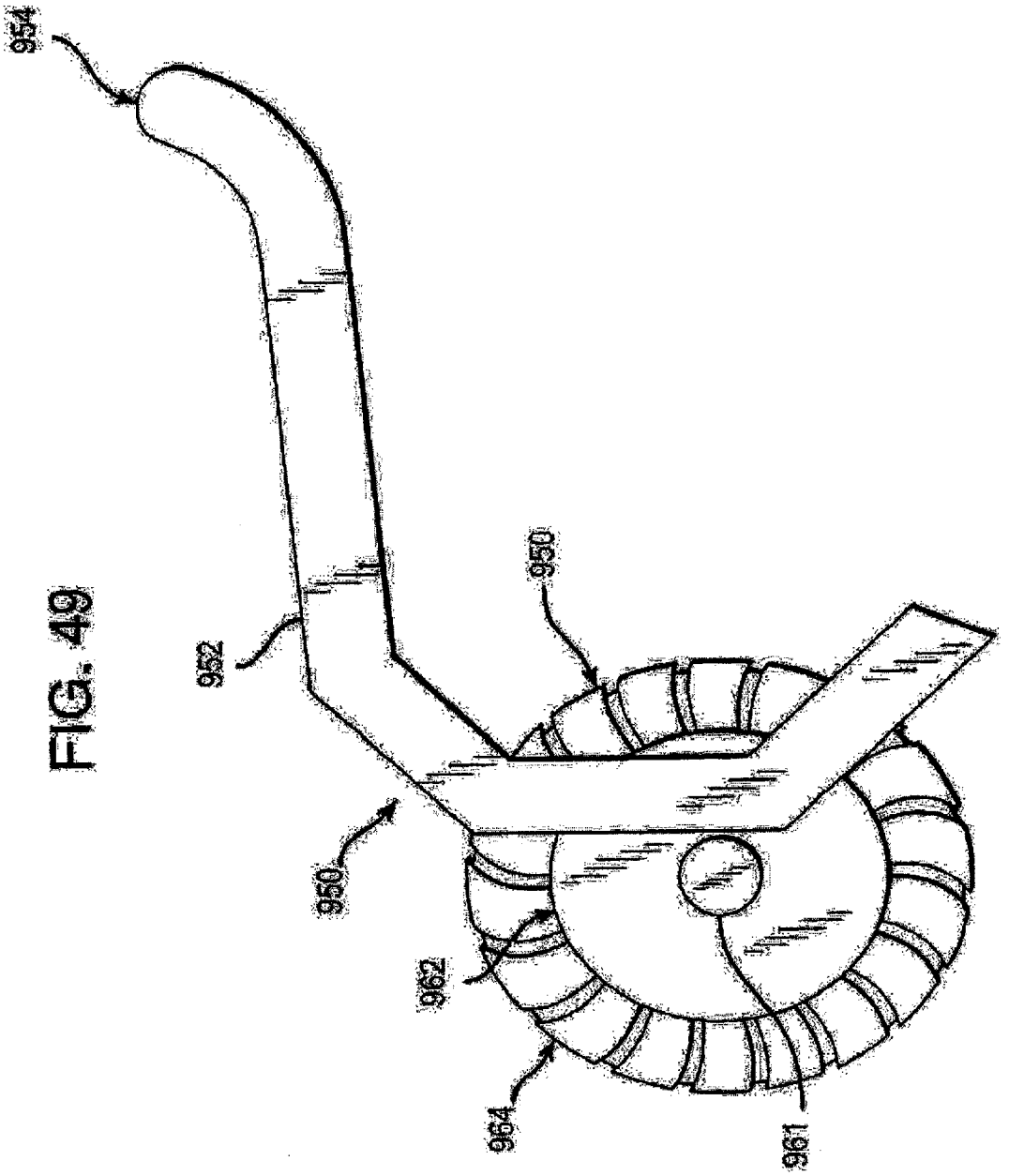
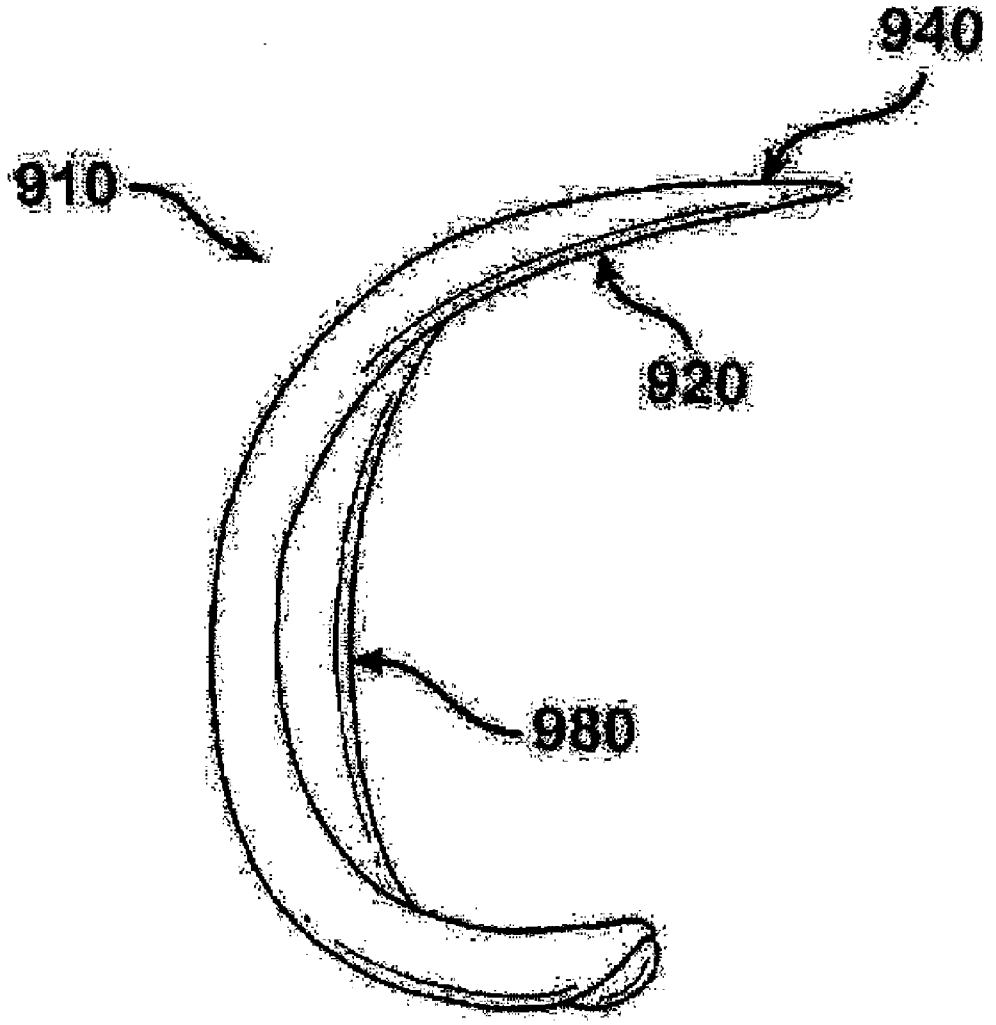


FIG. 50



METHODS AND APPARATUS FOR FEMORAL AND TIBIAL RESECTION

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 09/799,325 filed Mar. 5, 2001 now U.S. Pat. No. 6,695,848, which is a continuation-in-part of U.S. application Ser. No. 09/261,528, filed Mar. 3, 1999, now U.S. Pat. No. 6,197,064, which was a continuation of U.S. application Ser. No. 08/892,286 filed Jul. 14, 1997, now U.S. Pat. No. 5,879,354, which was a divisional of U.S. application Ser. No. 08/649,465, filed May 17, 1996, now U.S. Pat. No. 5,755,803, which was a continuation-in-part application of U.S. application Ser. No. 08/603,582, filed Feb. 20, 1996, now U.S. Pat. No. 5,810,827, which was a continuation-in-part application of U.S. application Ser. No. 08/300,379, filed Sep. 2, 1994, now U.S. Pat. No. 5,514,139, dated May 7, 1996, and which was also a continuation-in-part application of U.S. application Ser. No. 08/479,363, now U.S. Pat. No. 5,643,272, which is a continuation-in-part of U.S. application Ser. No. 08/342,143, filed Nov. 18, 1994, now U.S. Pat. No. 5,597,379, which is a continuation-in-part application of U.S. application Ser. No. 08/300,379, filed Sep. 2, 1994, now U.S. Pat. No. 5,514,139, dated May 7, 1996. U.S. Ser. No. 479,363. The entire disclosures of these related applications are expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention generally relates to methods and apparatus for femoral and tibial resection to allow for the interconnection or attachment of various prosthetic devices.

2. Related Art

Different methods and apparatus have been developed in the past to enable a surgeon to remove bony material to create specifically shaped surfaces in or on a bone for various reasons including to allow for attachment of various devices or objects to the bone. Keeping in mind that the ultimate goal of any surgical procedure is to restore the body to normal function, it is critical that the quality and orientation of the cut, as well as the quality of fixation, and the location and orientation of objects or devices attached to the bone, is sufficient to ensure proper healing of the body, as well as appropriate mechanical function of the musculoskeletal structure.

In total knee replacements, a series of planar and/or curvilinear surfaces, or "resections," are created to allow for the attachment of prosthetic or other devices to the femur, tibia and/or patella. In the case of the femur, it is common to use the central axis of the femur, the posterior and distal femoral condyles, and/or the anterior distal femoral cortex as guides to determine the location and orientation of distal femoral resections. The location and orientation of these resections are critical in that they dictate the final location and orientation of the distal femoral implant. It is commonly thought that the location and orientation of the distal femoral implant are critical factors in the success or failure of the artificial knee joint. Additionally, with any surgical procedure, time is critical, and methods and apparatus that can save operating room time, are valuable. Past efforts have not been successful in consistently and/or properly locating and orienting distal femoral resections in a quick and efficient manner.

The use of oscillating sawblade based resection systems has been the standard in total knee replacement for over 30 years. Due to their use of this sub-optimal cutting tool, the instrumentation systems all possess certain limitations and liabilities.

Perhaps the most critical factor in the clinical success of TKA is the accuracy of the implant's placement. This can be described by the degrees of freedom associated with each implant; for the femoral component these include location and orientation that may be described as Varus-Valgus Alignment, Rotational Alignment, Flexion-Extension Alignment, A-P location, Distal Resection Depth Location, and Mediolateral Location. Conventional instrumentation very often relies on the placement of 1/8 or 3/16 inch diameter pin or drill placement in the anterior or distal faces of the femur for placement of cutting guides. In the case of posterior referencing systems, the distal resection cutting guide is positioned by drilling two long drill bits into the anterior cortex. As these long drills contact the oblique surface of the femur they very often deflect, following the path of least resistance into the bone. As the alignment guides are disconnected from these cutting guides, the drill pins will "spring" to whatever position was dictated by their deflected course thus changing their designated, desired alignment to something less predictable and/or desirable. This kind of error is further compounded by the "tolerance stacking," inherent in the use of multiple alignment guides and cutting guides. Another error inherent in these systems further adding to mal-alignment is deflection of the oscillating sawblade during the cutting process. The use of an oscillating sawblade is very skill intensive as the blade will also follow the path of least resistance through the bone and deflect in a manner creating variations in the cut surfaces which further contribute to prosthesis mal-alignment as well as poor fit between the prosthesis and the resection surfaces. Despite the fact that the oscillating saw has been used in TKA for more than 30 years, orthopedic salespeople still report incidences where poor cuts result in significant gaps in the fit between the implant and the bone.

It is an often repeated rule of thumb for orthopedic surgeons that a "Well placed, but poorly designed implant will perform well clinically, while a poorly placed, well designed implant will perform poorly clinically." One of the primary goals of the invention described herein is to eliminate errors of this kind to create more reproducible, consistently excellent clinical results in a manner that requires minimal manual skill on the part of the surgeon.

None of the previous efforts of others disclose all of the benefits and advantages of the present invention, nor do the previous efforts of others teach or suggest all the elements of the present invention.

OBJECTS AND SUMMARY OF THE INVENTION

Many of the specific applications of the method and apparatus of the present invention described herein apply to total knee replacement, a surgical procedure wherein planar surfaces and/or curvilinear surfaces must be created in or on bone to allow for proper attachment or implantation of prosthetic devices. However, it should be noted that it is within the scope of the present invention to apply the methods and apparatus herein described to the removal of any kind of material from bones in any other application where it is necessary, desirable or useful to remove material from bones.

The apparatus of the present invention comprises a number of components including a positioning apparatus, a pattern apparatus and a cutting apparatus.

The pattern apparatus is oriented and located by the use of the positioning apparatus which references the geometry of a bone to be resected and/or other anatomic landmarks. When used to resect a distal femur, the positioning apparatus also references the long axis of the femur. Once the positioning apparatus has been properly located, aligned, and initially fixed in place, the pattern apparatus may be attached thereto, and then adjusted according to the preferences of the surgeon utilizing the apparatus, and then the pattern apparatus can be rigidly fixed to a bone to be resected. This ensures the pattern apparatus is properly located and oriented prior to the use of the cutting apparatus to remove material from the bone.

More specifically, when the method and apparatus of the present invention are used in connection with resecting a distal femur, the positioning apparatus is located and aligned utilizing the intramedullary canal of the femur, (thereby approximating the long axis of the femur), the distal surfaces of the femoral condyles, the anterior surface of the distal femur, and the posterior surfaces of the femoral condyles, which are referenced to indicate the appropriate location and orientation of the pattern apparatus. Fixation means may be used to fix the positioning apparatus, as well as the pattern apparatus to the distal femur. Means may be present in the positioning apparatus and/or pattern device for allowing the following additional adjustments in the location and orientation of the pattern device:

1. internal and external rotational adjustment;
2. varus and valgus angular adjustment;
3. anterior and posterior location adjustments;
4. proximal and distal location adjustment; and
5. flexion and extension angular adjustment.

Cannulated screws, fixation nails or other fixation means may then be used to firmly fix the pattern apparatus to the distal femur. The positioning apparatus may then be disconnected from the pattern apparatus and removed from the distal femur. Thus, the location and orientation of the pattern apparatus is established.

The pattern device possesses slot-like features, or a cutting path, having geometry that matches or relates to the desired geometry of the cut. When used in connection with resecting a knee, the cutting path resembles the interior profile of the distal femoral prosthesis. The cutting path guides the cutting apparatus to precisely and accurately remove material from the distal femur. Thus, the distal femur is thereby properly prepared to accept a properly aligned and located distal prosthesis.

In preparing a patella, the pattern device may be an integral part of the positioning apparatus which is oriented and located by referencing the geometry of the patella itself as well as the structures of the patellofemoral mechanism to determine the location and orientation of a predominantly planar resection. The cutting device may then be employed to perform the resection of the patella by traversing the path dictated by the pattern device, thus dictating the final location and orientation of the patella prosthesis.

The apparatus of the present invention comprises a number of components including an ankle clamp, an alignment rod, a fixation head, cutting guide clamps having an integral attachment mechanism, and a milling bit.

The method of present invention includes the steps of attaching the ankle clamp about the ankle, interconnecting the distal end of the alignment rod with the ankle clamp, interconnecting the fixation head with the proximal end of the alignment rod, partially attaching the fixation head to the proximal tibia, aligning the alignment rod, completely attaching the fixation head to the proximal tibia, interconnecting the cutting guide clamps with the alignment rod, positioning the cutting guide clamps about the proximal tibia, securing the cutting guide clamps to the tibia at a proper location, removing the fixation head, and cutting the proximal tibia with the milling bit.

The implant of the present invention has an outer bearing surface and an inner attachment surface. The outer bearing surface functions as a joint contact surface for the reconstructed bone. The inner attachment surface contacts a bone and is attached thereto. The inner attachment surface of the implant is curvilinear from an anterior to a posterior area of the femur, as is conventionally known, and is also curvilinear from a medial to a lateral area of the femur to approximate the shape of natural femur. The resection of the femur for accommodating the implant can be properly performed by a milling device employing one or more curvilinear milling bits.

There are numerous advantages associated with the curvilinear implant of the present invention. First, it will allow for a very thin implant cross-section and therefore necessitate the removal of the least amount of viable osseous tissue. Accordingly, the kinematics of the artificial joint could be made to be as close as possible to that of a healthy, natural knee joint. In addition, the curvilinear geometry of the implant dramatically decreases the stress risers inherent in conventional rectilinear femoral implants and allows for a thinner cross-sectional geometry while potentially increasing the resistance of the implant to mechanical failure under fatigue or impact loading. Conversely, the curvilinear geometry of the implant may also allow for an advantageous reduction in the flexural rigidity of the implant which may result in avoidance of the "stress-shielding" inherent in rigid implant designs.

This curvilinear implant of the present invention could also result in a less expensive femoral implant because of the reduced amount of material needed for the implant, as well as an improved, more natural, and even stronger knee replacement. The cross-section of the implant could be varied to assist in seating the implant and to increase the strength and fit of the implant. The implants of the present invention having curvilinear implant surfaces could be fabricated of metal, plastic, or ceramic or any other material. Further, the thickness of the implants and the material required to fabricate the implant could be reduced as the implants are adapted to increasingly curvilinear surfaces.

The resected surfaces of a femur or other bone to accept the implant of the present invention could be prepared by the apparatus and method for resection shown and described in the prior related applications set forth herein, the entire disclosures of which are expressly incorporated herein by reference.

The apparatus of the present invention comprises a number of components including a positioning and drill guide, a cutting guide and a cutting apparatus. The drill guide is used to create holes in the medial and lateral sides of the femur that correspond to the fixation features of the cutting guide. The cutting guide is oriented and located by inserting fixation nubs connected to the cutting guide into the medial and lateral holes in the femur. The cutting guide can then be further affixed to the femur. The cutting apparatus can then be used with the cutting guide to resect the femur. A conventional cutting block used with a conventional oscillating saw can also be positioned and interconnected with a femur in a similar manner using the drill guide of the present

invention to create medial and lateral holes. A cutting guide can then be attached to the holes. A conventional cutting block can be interconnected with the cutting guide for attachment of the block to the femur. This invention can also be used in connection with a cortical milling system, i.e., a cutting system for providing a curvilinear cutting path and curvilinear cutting profile. Likewise, a tibial cutting guide can similarly be positioned on a tibia with a drill guide.

It is a primary object of the present invention to provide an apparatus for properly resecting the distal human femur.

It is also an object of this invention to provide an apparatus for properly orienting a resection of the distal human femur.

It is an additional object of the resection apparatus of the present invention to properly locate the resection apparatus with respect to the distal human femur.

It is even another object of the resection apparatus of the present invention to properly orient the resection apparatus with respect to the distal human femur.

It is another object of the resection apparatus of the present invention to provide a guide device for establishing the location and orientation of the resection apparatus with respect to the distal human femur.

It is still a further object of the resection apparatus of the present invention to lessen the chances of fatty embolisms.

It is even a further object of this invention is to provide a resection apparatus capable of forming some or all of the resected surfaces of the distal human femur.

It is another object of the resection apparatus of the present invention to provide an apparatus which is simple in design and precise and accurate in operation.

It is also an intention of the resection apparatus of the present invention to provide a guide device for determining the location of the long axis of the femur while lessening the chances of fatty embolism.

It is also an object of the resection apparatus of the present invention to provide a device to physically remove material from the distal femur in a pattern dictated by the pattern device.

It is even another object of the resection apparatus of the present invention to provide a circular cutting blade for removing bone from the distal human femur to resection the distal human femur.

It is also an object of the present invention to provide a method for easily and accurately resecting a distal human femur.

These objects and others are met by the resection method and apparatus of the present invention.

It is a primary object of the present invention to provide methods and apparatus for femoral and tibial resection.

It is another object of the present invention to provide a method and apparatus for properly, accurately and quickly resecting a bone.

It is also an object of this invention to provide a method and apparatus for properly orienting and locating a resection of a bone.

It is a further object of the present invention to provide a method and apparatus to properly locate and orient the resection apparatus with respect to a bone.

It is another object of the present invention to provide methods and apparatus for femoral and tibial resection which are simple in design and precise and accurate in operation.

It is an additional object of the present invention to provide a method and apparatus to physically remove material from a bone in a pattern dictated by a pattern device and/or the geometry of a cutting device.

It is a further object of the present invention to provide methods and apparatus for resecting a bone which allows one to visually inspect the location of the cut or cuts prior to making the cut or cuts.

It is yet a further object of the present invention to provide a method and apparatus for resecting a bone which physically removes material from the bone along a surface dictated by a guide device.

It is still a further object of the present invention to provide a method and apparatus for resecting a bone which employs a milling bit or form cutter for removing material from the bone.

It is a further object of the present invention to provide methods and apparatus for femoral and tibial resection wherein the apparatus can be located on a bone to be cut in a quick, safe and accurate manner.

It is a primary object of the present invention to provide a method and apparatus for properly resecting the proximal human tibia in connection with knee replacement surgery.

It is also an object of the present invention to provide a method and apparatus for resecting the proximal human tibia which minimizes the skill necessary to complete the procedure.

It is another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which properly orients the resection of the proximal tibia.

It is even another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which is easy to use.

It is yet another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which orients the resection in accordance with what is desired in the art.

It is still yet another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which minimizes the amount of bone cut.

It is a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which allows one to visually inspect the location of the cut prior to making the cut.

It is even a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which is simple in design and precise and accurate in operation.

It is yet a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which physically removes material from the proximal tibia along a surface dictated by a guide device.

It is still a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which employs a milling bit for removing material from the proximal tibia.

It is also an object of the present invention to provide a method and apparatus for resecting the proximal human tibia which includes a component which is operated, and looks and functions, like pliers or clamps.

It is even another object of the present invention to provide an alternate embodiment of the method and apparatus for resecting the proximal human tibia which includes a component that resembles a U-shaped device for placing about the tibia.

It is even a further object of the present invention to provide an alternate embodiment of the method and apparatus for resecting the proximal human tibia which includes a component that resembles an adjustable, square, U-shaped device for placing about the tibia.

These objects and others are met and accomplished by the method and apparatus of the present invention for resecting the proximal tibia.

It is a primary object of the present invention to provide a method and apparatus for removing material from bones.

It is another object of the present invention to provide a method and apparatus for properly resecting bone.

It is also an object of this invention to provide a method and apparatus for properly orienting a resection of a bone.

It is a further object of the present invention to provide a method and apparatus to properly orient the resection apparatus with respect to a bone.

It is an additional object of the present invention to provide a method and apparatus for properly locating a bone resection.

It is a further object of the present invention to provide a method and apparatus to properly locate the resection apparatus with respect to a bone.

It is even another object of the resection apparatus of the present invention to provide a guide device and method of use thereof for establishing the location and orientation of the resection apparatus with respect to a bone.

It is an additional object of the present invention to provide a method and apparatus for making a curvilinear bone resection.

It is still a further object of the resection apparatus of the present invention to lessen the chances of fatty embolisms.

It is even further object of this invention to provide a method and apparatus capable of forming or re-forming some or all of the surfaces or resected surfaces of a bone.

It is another object of the present invention to provide a method and apparatus which is simple in design and precise and accurate in operation.

It is also an intention of the present invention to provide a method and apparatus for determining the location of the long axis of a bone while lessening the chances of fatty embolisms.

It is also an object of the present invention to provide a method and apparatus to physically remove material from a bone in a pattern.

It is an additional object of the present invention to provide a method and apparatus to physically remove material from a bone in a pattern dictated by a pattern device and/or the geometry of a cutting device.

It is even another object of the resection apparatus of the present invention to provide a cylindrical or semi-cylindrical cutting device and method of use thereof for removing material from a bone.

It is also an object of the present invention to provide a method and apparatus for easily and accurately resecting a bone.

It is also an object of the present invention to provide a method and apparatus for resecting a bone which minimizes the manual skill necessary to complete the procedure.

It is even another object of the present invention to provide a method and apparatus for resecting a bone which is easy to use.

It is still yet another object of the present invention to provide a method and apparatus for resecting a bone which minimizes the amount of bone removed.

It is a further object of the present invention to provide a method and apparatus for resecting a bone which allows one to visually inspect the location of the cut or cuts prior to making the cut or cuts.

It is yet a further object of the present invention to provide a method and apparatus for resecting a bone which physically removes material from the bone along a surface dictated by a guide device.

It is still a further object of the present invention to provide a method and apparatus for resecting a bone which employs a milling bit or form cutter for removing material from the bone.

It is even another object of the present invention to provide a method and apparatus for removing material from a bone such that both the cutting path and cutting profile are predominantly curvilinear.

It is a primary object of the present invention to provide an apparatus to properly replace damaged bony tissues.

It is also an object of this invention to provide an apparatus to properly replace damaged bony tissues in joint replacement surgery.

It is also an object of the present invention to provide an implant for the attachment to a distal femur in the context of knee replacement surgery.

It is an additional object of the present invention to provide a method and apparatus for making a curvilinear implant.

It is another object of the present invention to provide an implant having a reduced thickness to reduce the amount of material required to make the implant.

It is even another object of the present invention to provide an implant having curvilinear fixation surfaces for increasing the strength of the implant.

It is another object of the present invention to provide an implant having a fixation surface that is anterior-posterior curvilinear and mediolateral curvilinear.

It is another object of the present invention to provide an implant that has a fixation surface that is shaped to resemble a natural distal femur.

It is also an object of the present invention to provide an implant apparatus for allowing proper patellofemoral articulation.

It is a further object of the present invention to provide for minimal stress shielding of living bone through reduction of flexural rigidity.

It is an additional object of the present invention to provide an implant apparatus having internal fixation surfaces which allow for minimal bony material removal.

It is another object of the present invention to provide an implant apparatus with internal fixation surfaces that minimize stress risers.

It is another object of the present invention to provide an implant apparatus having internal fixation surfaces for precise fixation to curvilinear body resections.

It is another object of the present invention to provide an implant apparatus having internal fixation surfaces for precise apposition to curvilinear body resections.

It is another object of the present invention to provide an implant apparatus having internal fixation surfaces for curvilinear interior fixation geometries closely resembling the geometry of the external or articular geometry of the implant apparatus.

It is also an object of this invention to provide a method and apparatus for properly locating and orienting a prosthetic implant with respect to a bone.

It is another object of the present invention to provide an implant which is simple in design and precise and accurate in operation.

It is also an object of the present invention to provide an implant which minimizes the manual skill necessary to complete the procedure.

It is still yet another object of the present invention to provide an implant which minimizes the amount of bone removed.

It is even another object of the present invention to provide a method and apparatus for removing material from a bone such that both the cutting path and cutting profile are predominantly curvilinear.

BRIEF DESCRIPTION OF THE DRAWINGS

Other important objects and features of the invention will be apparent from the following detailed description of the invention taken in connection with the accompanying drawings in which:

FIG. **1**. is an exploded view of the resection apparatus of the present invention showing the positioning apparatus body, the angular adjustment component and the rotational alignment component.

FIG. **2** is a side plan view of the guide device of the resection apparatus of FIG. **1** attached to a distal human femur.

FIG. **3** is an exploded view of the pattern device of the resection apparatus of the present invention.

FIG. **4** is a side plan view of the resection apparatus shown in FIG. **2** with the pattern device fixed to the distal human femur.

FIG. **5** is an exploded front view of the cutting device of the resection apparatus of the present invention.

FIG. **6** is a top plan view of the pattern device and the cutting device of the resection apparatus of the present invention affixed to the distal human femur.

FIG. **7** is a side plan view of an intermedullary rod having a helical groove for use with the resection apparatus shown in FIG. **1**.

FIG. **8** is a partially exploded side plan view of an embodiment of the tibial resection apparatus of the present invention shown attached to the tibia, wherein the cutting guide clamps are of a fixed size and directly interconnect with the alignment rod.

FIG. **9** is a top plan view of the tibial resection apparatus, shown in FIG. **8** prior to insertion of the milling bit into the apparatus.

FIG. **10** is a partially exploded side plan view of another embodiment of the tibial resection apparatus shown in FIG. **8**, wherein the cutting guide clamps interconnect with the alignment rod by means of a cutting guide clamp linkage.

FIG. **11** is a side plan view of an embodiment of the cutting guide clamps shown in FIG. **8**, wherein the cutting guide clamps are adjustable.

FIG. **12** is a top plan view of the cutting guide clamps shown in FIG. **11**.

FIG. **13** is a perspective view of an embodiment of the tibial resection apparatus shown in FIG. **8**, showing the proximal tibial referencing stylus attached to the cutting guide clamps.

FIG. **14** is a cross-sectional view of the profile of the ends of the clamp members taken along line A-A in FIG. **12**.

FIG. **15** is a cross-sectional view of the profile of the ends of the cutting guides taken along line B-B in FIG. **12**, the ends of the clamps mating with the ends of the cutting guides for positioning the cutting guides with respect to the clamps.

FIG. **16** is a perspective view of an alternate embodiment of a U-shaped cutting guide for use in the present invention.

FIG. **17** is a top plan view of another alternate embodiment of a square U-shaped cutting guide for use in the present invention.

FIG. **18** is a perspective view of another alternate embodiment of a partial cutting guide for use in the present invention when the patellar tendon, patella, or quad tendon interferes with placement of the cutting guide about the tibia.

FIG. **19** is a rear perspective view of an embodiment of the pattern apparatus of the present invention.

FIG. **20** is a front perspective view of the pattern apparatus shown in FIG. **19**.

FIG. **21** is a partially exploded side plan view of the positioning apparatus shown in FIG. **19**.

FIG. **22** is an exploded perspective view of the cross-bar of the pattern apparatus shown in FIG. **19**.

FIG. **23** is a partially cut away side plan view of the pattern plate/cross-bar attachment linkage for interconnecting the pattern plate to the cross-bar as shown in FIG. **19**.

FIG. **24** is a perspective view of the positioning apparatus of the present invention.

FIG. **25** is a top plan view of the positioning apparatus shown in FIG. **24**.

FIG. **26** is an exploded perspective view of the positioning apparatus shown in FIG. **24**.

FIG. **27** is an exploded perspective view of the protractor rod guide assembly portion of the positioning apparatus shown in FIG. **24**.

FIGS. **28**A-**28**D are plan views of another embodiment of a rod guide assembly for use with the positioning apparatus shown in FIG. **24**.

FIG. **29** is a side plan view of an embodiment of the fixation device for affixing the pattern apparatus shown in FIG. **19** to a bone.

FIG. **30** is a partial side plan view of the pattern apparatus shown in FIG. **19**, showing the posterior/anterior referencing guide.

FIG. **31** is a side plan view of another embodiment of the pattern apparatus shown in FIG. **19**.

FIG. **32** is a side plan view of another embodiment of the positioning apparatus shown in FIG. **24** for use in performing ligament balancing; FIGS. **32**A and **32**B are cross-sectional views along section A-A in FIG. **32**.

FIGS. **33**A and B are front plan views of an embodiment of the cutting apparatus of the present invention for cutting a bone a in curvilinear cross-sectional plane.

FIG. **34** is a perspective view of a handle for guiding a milling bit along a cutting path.

FIG. **35** is a perspective view of another embodiment of the pattern apparatus shown in FIG. **19**, having a milling bit engaged therewith.

FIG. **36** is a side plan view of the pattern apparatus shown in FIG. **35** with the milling bit disengaged from the pattern apparatus.

FIG. **37** is another side plan view of the pattern apparatus shown in FIG. **36** showing the milling bit engaged with the pattern apparatus.

FIG. **38** is a perspective view of a femoral implant having a curved implant bearing surface.

FIG. **39** is a side plan view of the femoral implant shown in FIG. **38**.

FIG. **40** is a side plan view of another embodiment of the pattern apparatus and positioning apparatus of the present invention for resecting a patella.

FIG. **41** is a top plan view of the patella resection apparatus shown in FIG. **40**.

FIG. **42** is a front plan view of the patella resection apparatus shown in FIG. **40**.

FIG. **43** is a perspective view of another embodiment of the pattern apparatus of the present invention for cutting a bone.

FIG. **44** is a perspective view of another embodiment of the alignment apparatus shown in FIG. **24**.

FIG. **45** is a partially exploded side plan view of another embodiment of the pattern apparatus of the present invention for cutting a bone.

FIG. **46** is a partially exploded perspective view of the interconnection of a handle with milling bit for use in connection with pattern plate shown in FIG. **45**.

FIG. **47** is front plan view of another cutting apparatus for use in connection with the present invention.

FIG. **48** is a side plan view of the femoral implant shown in FIG. **38**, FIGS. **48**A, **48**B, **48**C and **48**D being sectional views taken along lines A-A, B-B, C-C and D-D of FIG. **48**, respectively.

FIG. **49** is a side plan view of the curvilinear milling bit and resection guide shown in FIG. **35**.

FIG. **50** is a side plan view of another embodiment of the femoral implant shown in FIG. **38**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown generally in FIGS. **1-6**, the resecting apparatus of the present invention comprises a number of components, namely positioning apparatus generally indicated at **10** comprising positioning body generally indicated at **12**, angular adjustment block generally indicated at **32**, rotational alignment device generally indicated at **50**, pattern device generally indicated at **59** and cutting means generally indicated at **90**.

As shown in detail in FIG. **1**, the positioning apparatus, generally indicated at **10**, includes a positioning body generally indicated at **12** having sides **13**, top surface **14**, front surface **15**, back surface **19** and cross member **18**. Extending from a lower end of the positioning body **12** is positioning tongue **20** having an upper surface **22**. Extending into the positioning body **12** from top surface **14** to the cross member **18** and through the front and back surfaces **15** and **19**, is a gap generally defined by slots **16** and partial slot walls **17**. Sides **13** include apertures **24** for receiving locking screws **25**. Also extending through the body **12** from the back surface **19** to the front surface **15** are apertures **27** for receiving fixation screws **26**.

The positioning apparatus **10** receives and holds angular adjustment block generally indicated at **32**. Angular adjustment block **32** includes a front surface **34** having wings **36** sized to be received by the slots **16** in the positioning body **12** to hold the angular adjustment block **32**. The angular adjustment block **32** is locked into place in the positioning body **12** by means of locking screws **25**, which extend through apertures **24** in the positioning body **12** and contact the wings **36** of the angular adjustment block **32** to secure the angular adjustment block **32** to the positioning body **12**. The angular adjustment block **32** establishes the angular alignment and anterior/posterior location of the positioning apparatus **10**.

The angular adjustment block **32** also includes back surface **38** and an aperture **40** extending from the back surface **38** through the angular adjustment block **32** to the front surface **34**. The aperture **40** receives an intermedullary rod **42** therethrough. The intermedullary rod **42** comprises a shaft **43** and a handle **44**. The shaft **43** extends through the angular adjustment block **32** and into the intermedullary canal which extends along the axis of the femur to aid in establishing the orientation of the resection apparatus of the present invention as hereinafter described.

The rotational alignment device, generally indicated at **50**, includes a shaft **51** having a groove **52** therealong and a block **53** having a back surface **54** and wings **56**. The rotational alignment device **50** is interconnected with the positioning body **12** by means of the wings **56** received in slots **16** of the positioning body **12**. The rotational alignment device **50** may be secured to the positioning body **12** by means of locking screws **25** which extend through apertures **24** in the positioning body **12** to contact the wings **56**. The locking screws **25** may be made of various configurations depending upon their specific function. Importantly, the locking screws **25** are used to rigidly affix one component or device to another to ensure that the relative locations and orientations are maintained despite the rigors of surgery.

As shown in FIG. **2**, wherein the positioning body **12** is fitted with the angular adjustment block **32** and the rotational alignment device **50**, the entire positioning apparatus **10** is connected to a human femur **7** by means of the shaft **43** of the intermedullary rod **42**. The shaft **43** extends through the angular adjustment block **32**, and thereby through the positioning body **12** into the intermedullary canal which extends along the axis of the femur **7**. The intermedullary rod **42**, shown in FIG. **7**, has a groove **41** transversing a helical path **45** along the axis of the shaft **43**. The groove **41** relieves intermedullary pressure that leads to fatty embolisms. The basic concept of the intermedullary rod **42** with the groove **41**, is that as it is inserted into the femur, which contains liquid fatty tissue, the liquid fatty tissue is drawn up the groove **41** of the intermedullary rod **42** to draw the fatty liquid tissue out of the femur. Preferably, the intermedullary rod would have a hexagonal head, (not shown) to permit it to be driven by a powered device such as an electrical hand held tool. Importantly, the groove **41** does not have a cutting edge, which would risk perforation of the femoral cortex. Accordingly, the device does not cut solid material, but removes liquid material from the intermedullary canal. Therefore, the risk of fatty embolism is reduced.

After positioning body **12** is properly located against the femur **7** by means of the intermedullary rod **42** and the angular adjustment block **32**, fixation screws **26** may be advanced through the apertures **27** in the positioning body **12** until they make contact with the distal femoral condyles of the femur **7**, and are then driven into the distal femoral condyles of the femur **7** to initially affix the positioning apparatus to the distal femur **7**. It should be noted that the fixation screws **26** may also be advanced and adjusted to make up for deficiencies in the distal femoral condyles. Accordingly, the positioning body **12** is positioned such that the front surface **15** is put into contact with the distal femoral condyles by direct contact, and the tongue **20** is positioned under the femur **7** and in contact therewith.

As can be seen in FIG. **2**, the shaft **51** of the rotational alignment device **50** extends above the femur **7** and allows for rotation of the pattern device **59**, hereinafter described, about the distal femur **7**. Additionally, the rotational alignment device **50** allows for the anterior/posterior positioning of the pattern device **59** with respect to the femur **7**. Importantly, the configurations of the positioning body **12**, the angular adjustment block **32** and the rotational alignment device **50** are not limited to the structure set forth herein, but may be of different shapes and may interconnect in different ways. These components may even be formed as a unitary or partially unitary device.

As shown in FIG. **3**, the pattern device **59** includes pattern plates **60** having tops **61**, and cutting paths, generally indicated at **62**, extending therethrough. The cutting paths **62** outline the desired resection shape of the distal femur **7**.

Generally, the cutting paths **62** could include a first vertical path **64**, extending to a first diagonal path **65**, extending to a second diagonal path **66**, extending to a second vertical path **67**, extending to a third diagonal path **68** and then extending to a horizontal path **69**. Alternatively, the cutting paths **62** could describe any desired resection shape for the femur **7**. The pattern plates **60** also include locking screws **75** for interconnecting the pattern plates **60** with a crossbar **80**.

The pattern device **59** of the present invention preferably includes two pattern plates **60** held in a spaced apart relationship by crossbar **80**. The crossbar **80** separates the pattern plates **60** sufficiently to permit the pattern plates **60** to extend along the sides of the distal femur **7**. The crossbar **80** includes a front surface **82**, back surface **84**, a top surface **83**, a central aperture **86** extending from the front surface **82** to the back surface **84**, a lock aperture **88** extending through the top surface **83**, and a lock screw **89**. The central aperture **86** of the crossbar **80** receives the shaft **51** of the rotational alignment device **50**. Accordingly, the pattern device **59** is interconnected with the positioning apparatus **10** so that the pattern device **59** is properly oriented with respect to the femur **7**. Upon proper positioning of the crossbar **80**, with respect to the shaft **51** of the rotational alignment device **50**, lock screw **89** is extended through lock aperture **88** to contact the shaft **51** to lock the crossbar **80** and, accordingly, the pattern device **59**, onto the shaft **51** of the rotational alignment device **50**, and accordingly, to positioning apparatus **10**. This completed assembly is attached to the femur **7**, as shown in FIG. **4**.

As additionally shown in FIGS. **3** and **4**, the pattern plates **60** include plate apertures **72** for receiving cannulated screws **70** which have apertures extending therethrough for receiving fixation nails **71** therethrough. Accordingly, after the pattern device **59** is interconnected with the positioning apparatus **10**, and properly located and oriented with respect to the femur **7**, the cannulated screws **70** are extended through the plate aperture **72** to contact the sides of the distal femur **7**. Then, in order to fix the pattern plates **60** with respect to the femur **7**, the fixation nails **71** are driven into the distal femur **7** to lock the pattern plate **60** into position on the distal femur **7**. The cannulated screws **70** have sharp leading edges for allowing decisive purchase in the distal femur **7** before the introduction of the fixation nails **71** to complete fixation of the pattern device **59** to the distal femur **7**.

The pattern plates **60** by virtue of the cutting paths **62**, dictate the shape of the resection of the femur **7**. The cutting paths **62** are essentially channels through the pattern plates **60**. The cutting paths **62** receive the cutting device and guide it as it resects the surface of the distal femur **7**. The pattern plates **60** straddle the distal femur **7** mediolaterally and are suspended by the crossbar **80**. Likewise, crossbar **80** maintains the proper relationship between the pattern plates **60** before and during the resection of the distal femur **7**. The location of the crossbar **80** and accordingly, the pattern plates **60**, may be adjusted with respect to the positioning apparatus **10** by adjusting the position of the block **53** of the rotational alignment device **50** within the slots **16** of the positioning body **12**, and locking the same with locking screws **25**.

The cutting paths **62** in the pattern plates **60** receive and guide the cutting device shown in FIG. **5** and generally indicated at **90**. The cutting device **90** performs the actual cutting of the femur **7** to resect the femur **7**. The cutting device may be of any known configuration. In a preferred embodiment, the cutting device is a drill. The drill **90** is generally cylindrical in shape and may possess helical cutting teeth along its length to cut the femur **7**. The drill **90** includes a hexagonal end **95** to permit the use of an electric powered drive, typically an electric drill. Further, the drill **90** includes drill bushings **92** at the ends of the drill **90** to provide a non-metallic bearing between the cutting paths **62** in the pattern plates **60** to avoid galling and to ensure smooth articulation of the drill **90** along the cutting path **62**. Positioned between the drill bushings **92** and the drill **90** are retention springs **94** which are essentially coil springs retained within the drill bushings **92** to allow the drill bushings **92** to be easily attached and removed from the drill **90**. These retention springs **94** are commercially available in medical grade stainless steels. The drill bushings **92** retain the retention springs **94** which hold the drill bushings **92** in position **92** on the drill **90** while allowing the drill bushings **92** to rotate freely. The drill **90** may also include circumferential grooves **91** for allowing attachment and retention of the drill bushings **92** by means of the retention springs **94**. Importantly, the configuration of the drill **90** can vary in accordance with what is known in the art, as long as the cutting device can follow the cutting paths **62** in the pattern plates **60** to resect the femur **7**.

As shown in FIG. **6**, after the pattern device **59** is attached to the distal femur **7**, and positioned accordingly by means of the positioning apparatus **10**, and secured to the distal femur **7** by means of cannulated screws **70** and fixation nails **71**, positioning apparatus **10** may be removed from connection to the distal femur **7** leaving the pattern device **59** attached to the distal femur **7** to permit resecting of the distal femur. The drill **90** is then positioned within the cutting paths **62** between the pattern plates **60**. Next the drill **90** is rotated by power means in connection with the hexagonal end **95**, and is then moved along the cutting path **62** to resect the distal femur **7**. It should also be noted that the cutting means could be operated by hand.

Instead of two pattern plates **60**, a single pattern plate could be employed if it is sufficiently sturdy to support and guide the drill. The pattern plates **60** may also comprise plates having edges in the shape of the desired distal femoral resection pattern. Thus, the cutting device may be drawn along the edges of the pattern plates to resect the distal femur. Further, any cutting device that can be employed to follow the cutting paths in the pattern plates is considered to be within the scope of this invention.

The resection apparatus of the present invention, through proper use as previously described, provides extremely accurate and reproducible bone cuts. While the anterior and distal areas of the femur will almost always be able to be prepared in this manner, interference from soft tissue such as fat and ligaments may prohibit satisfactory preparation of the posterior femur. The preparation of any remaining femoral surfaces may be completed in any manner known in the art after using the instrumentation of the present invention.

As shown in FIGS. **8-13**, the tibial resection apparatus of the present invention includes a number of components, namely, cutting guide clamps generally indicated at **210**, cutting guides generally indicated at **220**, ankle clamp generally indicated at **250**, alignment rod generally indicated at **260**, cutting guide clamp linkage generally indicated at **270**, fixation block generally indicated at **280**, proximal tibial referencing stylus generally indicated at **290**, and milling bit generally indicated at **255**. It should be noted that the cutting guides **220** may be formed integrally with the cutting guide clamps **210** as shown in FIGS. **8** and **9**, or as separate members as shown in FIGS. **11**, **12** and **13**. Also, the cutting guides **220** may ride the alignment **260** as shown in

FIGS. **8** and **9**, or they may interconnect with the alignment rod **260** by means of cutting guide clamp linkage **270**, as shown in FIGS. **11**, **12** and **13**.

As shown in FIG. **8**, the ankle clamp **250** is attached at or just above the ankle and exterior to the skin. Any conventional ankle clamp may be used to firmly engage the ankle, or to engage the tibia above the ankle, to obtain a reference point for the other components of the present invention.

The ankle clamp is interconnected with and locked into place on the alignment rod **260** in any way known in the art. Preferably, though not necessarily, the alignment rod **260** is vertically adjustable with respect to the ankle clamp **250**. This vertical adjustment can be achieved at the ankle clamp **250**, at the interconnection of the ankle clamp **250** and the alignment rod **260**, or within the alignment rod **260** itself. As shown in FIG. **8**, the alignment rod includes a first lower end **262** having an aperture **263** extending vertically therein for telescopically receiving a second upper end **265** of the alignment rod **260**. A set screw **264** is provided for fixing the upper end **265** with respect to the lower end **262**.

The fixation block **280** is interconnected with an upper end of the alignment rod **260** by means of an aperture **282** in the fixation block **280** sized to receive the alignment rod **260** therethrough, or in any other manner known in the art. A set screw **284** may be provided to extend into the fixation block **280**, through set screw aperture **286** in fixation block **280**, to contact the alignment rod **260**, to lock the fixation block **280** onto the alignment rod **260**. The fixation block **280** additionally includes apertures extending vertically therethrough for receiving fixation pins **288** for affixing the fixation block **280** to the proximal tibia **208**.

In operation, the ankle clamp **250** is attached about the ankle, or about the tibia just above the ankle, on the exterior of the skin. The fixation block **280** is already interconnected with the alignment rod **260**. It is preliminarily positioned over the proximal tibia **208**, and one of the fixation pins **288** is driven into the proximal tibia **208**. Thereafter, the alignment rod **260** is adjusted to establish proper varus/valgus alignment and flexion/extension angulation as is conventionally known. Upon proper alignment of the alignment rod **260**, the other fixation pin **288** is driven into the proximal tibia **208** to completely fix the fixation block **280** to the proximal tibia **208** to lock in the proper alignment of the alignment rod **260**. Then, the fixation block **280** may be locked into position on the alignment rod **260**.

After properly aligning and locking in the alignment of the alignment rod **260**, the cutting guide clamps **210** and the cutting guides **220** may be employed. The cutting guide clamps **210** are interconnected with the alignment rod **260** by means of cutting guide linkage **270**. Alternatively, the cutting guide clamps **210** could directly interconnect with the alignment rod **260** through apertures in the cutting guide clamps **210**, as shown in FIGS. **8** and **9**. As shown in FIG. **10**, the cutting guide clamp linkage **270** comprises a body **271** having an alignment rod aperture **272** for receiving and riding the alignment rod **260** and a pivot locking set screw **274** which extends into the cutting guide clamp linkage **270** through set screw aperture **275** for contacting the alignment rod **260** and locking the cutting guide clamp linkage **270** with respect to the alignment rod **260**. It should be pointed out that it may be desirable for the alignment rod **260** to have a flattened surface extending longitudinally along the alignment rod **260** for co-acting with set screw **274** for maintaining proper alignment between the cutting guide clamp linkage **270** and the alignment rod **260**.

The cutting guide clamp linkage **270** also includes a pivot shaft **276** rigidly interconnected with the body **271** of the cutting guide clamp linkage **270** by member **277** to position the pivot shaft **276** a distance away from the body **271** such that the cutting guide clamps **210** can be interconnected with the pivot shaft **276** and can be properly utilized without interfering with the body **271** of the cutting guide clamp linkage **270**.

After the alignment rod **260** is properly aligned and locked into position, the cutting guide clamp linkage **270** is moved into its approximate desired position at the proximal tibia **208**. It should be noted that the cutting guide clamp linkage **270** of present invention is positioned on the alignment rod **260** at the beginning of the procedure, prior to aligning the alignment rod **260**, and prior to interconnecting the fixation block **280** with the alignment rod **260**. However, it is within the scope of the present invention to provide a cutting guide clamp linkage **270** which is attachable to the alignment rod **260** after the alignment rod **260** has been aligned and locked into position.

After the cutting guide clamp linkage **270** is preliminarily approximately located, it is locked into place on the alignment rod **260**. Thereafter, the cutting guide clamps **210** may be interconnected with the pivot shaft **276** by means of corresponding pivot apertures **217** in the cutting guide clamps **210**.

As shown in FIGS. **11** and **12**, the cutting guide clamps **210** include opposing hand grips **212** for grasping and manipulating the cutting guide clamps **210**. Crossbar members **214** extend from the hand grips **212** to clamp members **218**. The crossbar members **214** cross over each other at cross over point **215** whereat the crossbar members **214** have mating recessed portions **216** which function to maintain the hand grips **212** in the same plane as the clamp members **218**. At the cross over point **215**, the crossbar members **214** can pivot with respect to each other such that movement of the hand grips **212** towards each other moves the clamp members **218** together, and likewise, movement of the hand grip members **212** away from each other serves to move the clamp members **218** apart in the same manner as scissors or pliers. At the cross over point **215**, the crossbar members **214** have corresponding pivot apertures **217** for receiving the pivot shaft **276** of the cutting guide clamp linkage **270**. Thus, the cutting guide clamps **210** pivot about the pivot shaft **276** of the cutting guide clamp linkage **270**. It should be noted that the crossbar members **214** could be interconnected with each other by a rivet or other means known in the art, or could be entirely independent pieces which co-act as set forth above only upon being seated on pivot shaft **276**.

The clamp members **218** of the cutting guide clamps **210** include cutting guide adjustment screw apertures **219** at the far ends thereof for receiving A-P adjustment screws **230** for adjustably interconnecting the cutting guides **220** with the clamp members **218**, for adjustable movement in the direction shown by arrow C in FIG. **11**. The clamp members **218** may be adjustably interconnected with the cutting guides **220** in any way known in the art. In one embodiment, the cutting guide adjustment screw apertures **218** are threaded and the cutting guides **220** have corresponding elongated apertures **228** extending over a portion of the length thereof for receiving the A-P adjustment screws at a desired location therealong. The A-P adjustment screws include a head **231**, a retaining head **232**, and a threaded shaft **234**. When the cutting guides **220** are positioned correctly with respect to the clamp members **218**, the A-P adjustment screws **230** are tightened down to lock the cutting guides **220** onto the clamp members **218** by actuating the head **231** to turn down the threaded shaft **234** with respect to the clamp member **218**. Note the retaining head **232** of the A-P adjustment screws

prevent the shaft **234** from being backed off out of engagement with the clamp member **218**.

As shown in FIGS. **14** and **15**, respectively, the clamp members **218** are shaped with opposing interior edges having chamfers **238** and the opposite exterior edges of the cutting guides **220** have mating recesses **239**, both of said profiles extending along the contacting surfaces of the clamp members **218**, as seen along line A-A in FIG. **12**, and the cutting guides **220**, as seen along line B-B in FIG. **12**, to maintain a proper planar alignment therebetween. It should of course be noted that any other method known in the art may be employed to maintain the clamp members **218** and the cutting guides **220** in alignment. Additionally, the cutting guides **220** may include A-P adjustment screw recesses **237** for receiving the head **231** of the A-P adjustment screw **230**.

The cutting guides **220** further include tibia attachment means for attaching the cutting guides **220** to the tibia **208**. Any known attachment means may be employed to attach the cutting guides **220** to the tibia **208**. As shown in FIGS. **9** and **11**, a preferred attachment means for attaching the cutting guides **220** to the tibia **208** are pins **236** extending through pin apertures **227** in the cutting guides **220**. The pins **236** may be captured in the pin apertures **227**, or they may be entirely separate. Preferably, means exist on the cutting guides **220** for preliminarily attaching the cutting guides **220** to the tibia **208** prior to pinning the cutting guides **220** thereto, so that after proper positioning of the cutting guides **220**, the hand grips **212** can be actuated by squeezing the hand grips **212** together to contact the cutting guides **220** against the tibia **208** so that the cutting guides **220** are preliminarily attached to the tibia **208**. Such means may include a plurality of small pins captured by the cutting guide **220**, or any other suitable means. After the preliminary attachment of the cutting guides **220** to the tibia **208**, final attachment may be made by attachment pins **236** or by any other means known in the art.

The cutting guides **220**, importantly, include cutting slots **222** which each comprise lower cutting slot guide surface **223** and upper cutting slot retaining surface **225**, as well as cutting slot entrance and exit **224** at one end thereof and cutting slot end wall **226** at the other end thereof. The cutting slot **222** is of a length sufficient to extend across the proximal tibia **208**, at a desired angle to the intermedullary canal, at the widest point of the proximal tibia **208**, to allow the entire upper surface of the proximal tibia **208** to be cut. The cutting slot **222** is of a size sufficient to receive a cylindrical milling bit **255** such as that shown in FIG. **16** and described in U.S. Pat. No. 5,514,139, filed Sep. 2, 1994 by Goldstein, et al. The milling bit **255** comprises central cutting portion **257** having helical cutting teeth along its length for cutting bone. The milling bit **255** further comprises spindles **256** extending from the central cutting portion **257** for supporting the central cutting portion **257**.

The milling bit **255** is inserted into and received in the cutting slot **222** through cutting slot entrance **224**, along the direction shown by arrow A in FIG. **16**. Note that the cutting slot entrance **224** may be of a wider slot area or an upturned portion of the slot **222** or the milling bit **255** may merely be inserted and removed from the slot **222** at an end thereof. The spindles **256** extend through and co-act with the lower cutting guide surface **223** and the upper retaining surface **225** of the cutting slot **222** to guide the milling bit **255** along the cutting slot **222** to resect the proximal tibia **208**, along the direction shown by arrow B in FIG. **16**. At an end of one or both of the spindles **256** is a means for engaging the milling bit **255** with a drive means such as an electric drill, or other drive means. This engagement means may include a hexagonal head on one of the spindles, or any other suitable method of engagement known in the art. Additionally, bushings may be employed, either on the milling bit **255** or captured by the cutting slot **222**, to provide a non-metallic bearing between the spindles **256** of the milling bit **255** and the cutting slot **222** to avoid galling and to ensure smooth articulation of the milling bit **255** along the cutting slots **222**. Importantly, the configuration of the milling bit **255** may be varied in accordance with what is known in the art, as long as the cutting device can follow the cutting path of the cutting slot to resect the proximal tibia. Additionally, it should also be pointed out that other cutting tools may be used in accordance with the present invention, including an oscillating or reciprocating saw or other means for resecting the tibia by following the cutting slots on the cutting guides.

After the cutting guide clamps **210** are preliminarily located along the alignment rod **260**, the cutting guides **220** are adjusted with respect to the clamp members **218** for proper anterior-posterior positioning to extend along the proximal tibia **208** for guiding the milling bit **255**. Importantly, the cutting slots **222** should extend beyond the edges of the proximal tibia **208**. Once proper anterior-posterior alignment is obtained, the cutting guides **220** may be locked into place on the clamp members **218**.

Thereafter, a proximal tibial referencing stylus **290** may be attached to a referencing bracket **292** on the cutting guides **220**. The referencing bracket **292** may be positioned in any location on the cutting guides **220**, or on any other convenient component of the tibia resection system of the present invention. Alternatively, the referencing stylus **290** may be formed as part of a component of the present invention, or as a separate component which could function merely by contacting the cutting guides **220** of the present invention or any other component thereof. The referencing stylus **290**, shown in FIG. **13**, includes stylus body **294** which may be interconnected with the referencing bracket **292** in any manner known in the art, preferably by a quick release and connect mechanism or a threaded connection. The stylus body **294** supports a stylus arm **296**, which is rotatable with respect to the stylus body **294** and configured to extend out and down from the stylus body **294** to contact the proximal tibia **208** at a tip **298** of the stylus arm **296**. The stylus body **294**, arm **296** and tip **298** are sized to contact the proximal tibia **208** to reference the positioning of the cutting guides **220** to cut the proximal tibia at a proper distance below the proximal tibia **208** as is known in the art. The stylus arm **296** may include more than one tip **298**, such other tips extending down from the stylus body **294** in varying distances.

In operation, one determines the desired location of the stylus tip **298**, unlocks the cutting guide clamp linkage **270** to permit the linkage **270** to move up and down the alignment rod **260**, and places the tip **298** on the lowest point of the proximal tibia **208** to reference the position of the cutting guides with respect to the proximal tibia **208** and with respect to the alignment rod **260**. Thereafter, the cutting guide clamp linkage **270** is locked to the alignment rod **260** to lock the cutting guides **220** into the proper position on the alignment rod **260**, and accordingly, into proper position with respect to the proximal tibia **208**. Thereafter, the hand grips **212** are actuated to press the cutting guides **220** against the proximal tibia **208** to preliminarily lock them into position on the proximal tibia **208**. Next, the cutting guides **220** are fixed to the proximal tibia **208** by pins **236** or any other desired fixation means. The fixation block **280** can then be removed from the proximal tibia **208**, and the proximal tibia **208** may be resected.

The cutting operation is similar to the cutting operation set forth in U.S. Pat. No. 5,514,139, filed Sep. 2, 1994 by Goldstein, et al. Essentially, the cutting operation comprises inserting the milling bit **255** into the cutting guide slots **222** through the slot entrance/exit **224** to position the central cutting portion **257** between the cutting guides **220**, the spindles **256** extending through the cutting guide slots **222**. After the milling bit **255** is positioned, the drive means may be interconnected therewith, actuated, and the milling bit **255** moved along the cutting slots **222** to resect the proximal tibia **208**.

It should be noted that a handle may be provided for attachment to the spindle which is not driven so that such spindle may be guided evenly through the cutting slots **222** to facilitate the cutting procedure. Alternatively, a handle can be provided which interconnects with both spindles to further facilitate control of the milling bit **255** during the cutting procedure. Additionally, the bushings that fit over the spindles **256** of milling bit **255** and ride in the cutting slots **222** may be captured in the ends of the handle and the milling bit received therethrough.

Additionally, it should be pointed out that it is within the scope of the present invention to modify the cutting slots **222** such that the upper retaining surface is eliminated, and the milling bit **255** merely follows the lower cutting guide surface **223**. With the cylindrical milling bit **255** herein described, this is especially viable as the milling bit **255** tends to pull down into the bone as it is cutting, thereby primarily utilizing the lower cutting guide surface **223** of the cutting guide **220**.

As shown in FIGS. **16-18**, various other embodiments of the cutting guides are considered within the scope of the present invention. The cutting guide **320** shown in FIG. **16** is of a generally U-shaped configuration, having cutting guide slots **322**, lower cutting guide surface **323**, upper retaining surface **325**, pin apertures **327** and alignment rod aperture **328**. This cutting guide **320** is used in the same manner as the cutting guides hereinbefore described, the differences being that the cutting guide **320** interconnects directly with the alignment rod and that various size cutting guides must be provided to accommodate various sized tibias.

Likewise, the cutting guide **320**, shown in FIG. **17**, operates in the same manner as the cutting guide devices hereinbefore described, but it does not include cutting guide clamps. The cutting guide **320** includes cutting slots **322**, and it interconnects directly with alignment rod by means of aperture **328**. The distance between facing members **330** can be adjusted by moving base members **332** and **334** with respect to each other to size the cutting guide **320** for the tibia to be cut. Upon proper sizing, the base members **332** and **334** may be locked with respect to each other by set screw **336** or any other means known in the art.

FIG. **18** shows an embodiment of the cutting guide for use when the patellar tendon, the patella, or the quad tendon interferes with the placement of the other cutting guides of the present invention. As shown in FIG. **18**, the cutting guide **350** may be directly interconnected with the alignment rod, and positioned on the tibia as hereinbefore set forth. Basically, this embodiment of the invention includes only one cutting guide. The cutting guide **350** and the cutting guide slot **322** may be wider than in the previous embodiments to help stabilize the milling bit in operation. In this embodiment, the milling bit may be first plunged across the tibia, and then moved therealong. The milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to the tissue about the tibia. Additionally, a support member, not shown, could be provided to extend from the cutting guide **350**, over and across the tibia to the other side thereof where it could have a slot to capture the milling bit and provide additional support thereto. The reference numerals **338**, **360** and **392** correspond to the reference numerals **238**, **260** and **292** respectively.

As shown generally in FIGS. **19-23**, the pattern apparatus of the present invention, generally indicated at **430**, comprises pattern plates, generally indicated at **432**, and crossbar apparatus, generally indicated at **440**.

Pattern Plates

Pattern plates **432** include fixation apertures **434** extending therethrough for accepting fixation means, as will hereinafter be described, for affixing the pattern plates **432** to a bone. The pattern plates **432** further include a cutting path **436** for dictating the path along which a bone is to be cut. As shown in FIGS. **19-23**, which are directed to an embodiment of the present invention for resecting a distal femur, the cutting path **436** in the pattern plates **432** matches the profile of a femoral component of a knee prosthesis for resecting the femur to accept the femoral component of the prosthesis. Importantly, as will hereinafter be described, the cutting path **436** could be identical in size and shape to an interior bearing surface of a femoral component of the knee prosthesis, or could vary in size and shape in accordance with alternative methods and apparatus used to perform the resection. For example, the cutting path could be larger than the desired resection, but a larger cutting tool could be used to arrive at a resection of the desired the desired size.

In the embodiment of the present invention shown in FIG. **21**, the cutting path **436** includes an anterior end **436**A, an anterior cut portion **436**B, an anterior chamfer portion **436**C, a distal cut portion **436**D, a posterior chamfer portion **436**E, a posterior cut portion **436**F, and a posterior end **436**G. Alternatively, the cutting path **436** could be of any desired shape in accordance with the prosthesis systems of the various manufacturers of such prosthesis, the desires of the surgeon utilizing the apparatus and/or the application for which a bone is to be cut.

Although a single pattern plate **432** may be employed in resecting a femur or other bone (and in some cases, i.e., a partial femur resection, it may be preferable to employ a single pattern plate **432**), two pattern plates **432** are generally employed to co-act with each other to support a cutting means on two sides of a bone to be cut. In the case of resecting a femur, a preferred embodiment of the present invention, as shown in FIGS. **19-21**, comprises two pattern plates **432** positioned on opposing sides of a femur. The pattern plates **432** are interconnected with each other, and maintained in proper alignment with respect to each other by a crossbar apparatus generally indicated at **440**, to straddle a bone. The pattern plates **432** include crossbar apertures **438** for interconnecting with the crossbar apparatus **440**. The pattern plates may also include crossbar slots **439** for permitting quick connect/disconnect between the pattern plates **432** and the crossbar apparatus **440**. Of course, it should be noted that the pattern plates **432** could interconnect with the crossbar in any other manner known in the art, or especially with bone cutting applications other than resecting the femur, the pattern plates **432** could be used without a crossbar.

Crossbar Apparatus

The crossbar apparatus **440** includes a number of component parts, namely, T-bar **442** having a top **444** and a stem **446** interconnected with and extending from the top **444** in

the same plane. The T-bar **442**, shown in the figures, comprises a flat metal member having a uniform rectangular cross-section through both the top **444** and the stem **446**. Three threaded lock apertures **448** are formed through the T-bar **442**, one at each end of the top **444** and at the far end of the stem **446**. Lock screws **450**, having gripable heads **452** and shafts **454** with threaded waists **456**, threadably engage the threaded lock apertures **448** in the T-bar **442**. The lock screws **450** further include pin holes **458** extending radially through the shafts **454** at the terminal ends thereof for receiving pins **459** for capturing the lock screws **450** on the T-bar **442**.

The crossbar apparatus **440** further includes linkages **460** having a first end for interconnection with the T-bar **442** and a second end for supporting and engaging pattern plates **432**. The first ends of the linkage **460** include a lower flat surface **462** for contacting the T-bar **442**, overhanging shoulders **464** for contacting the sides of the T-bar **442**, and an upper flat surface **466** for contact with the lock screws **450** for locking the linkages **460** onto the T-bar **442**. As shown in detail in FIG. **23**, the second ends of the linkage **460** include cylindrical supports **468** for supporting the pattern plates **432** thereon. The cylindrical supports **468** include axial extending apertures **469** for receiving capture pins **470** therethrough, the capture pins **470** including flanged ends **472** and threaded ends **474**. The capture pins **470** serve to capture pattern lock nuts **476** on the linkages **460**, the capture pins **470** extending through the axial apertures **469**, the flanged ends **472** retaining the capture pins **470** therein, the threaded ends **474** extending out of the cylindrical supports **469** and into the threaded interior **477** of the pattern lock nuts **476**. The cylindrical supports **468** receive the crossbar apertures **438** of the pattern plates **432** and the pattern lock nuts **476** are threaded down onto the capture pins **470** to secure the pattern plates **432** to the crossbar apparatus **440**. Of course, other embodiments of the crossbar apparatus sufficient for supporting the pattern plates of the present invention are considered within the scope of the present invention.

Positioning Apparatus

As shown in FIGS. **24-28**, the positioning apparatus of the present invention is generally indicated at **510**. The positioning apparatus generally comprises positioning body **520** and alignment apparatus **580**. The positioning body **520** comprises a frame **522** having sides **524**, bottom **526** and top **528** arranged to form a frame having a rectangular aperture defined therewithin. The top **528** further includes a head **530** formed thereon having a linkage aperture **532** extending therethrough at an upper end thereof, and having a lock aperture **534** extending from the upper edge of the head to the linkage aperture **532**. A lock screw **536** having a threaded shaft **538** extends into and is threadably engaged with the lock aperture **534** for locking the head **530** to a linkage, namely crossbar linkage **540**. Crossbar linkage **540** includes a first end having an upper flat surface **542** for interconnecting with the crossbar in a manner similar to the pattern plate linkages for attaching the pattern plates to the crossbar as hereinbefore described. The crossbar linkage **540** further includes a shaft **544** which is received by the linkage aperture **532** in the head **530** to interconnect the positioning body **520** with the crossbar linkage **540** and hence with the crossbar apparatus **440** and the pattern apparatus **430**. The positioning body can then be locked onto the crossbar linkage **540** by means of lock screw **536**.

The end of shaft **544** of the crossbar linkage **540** includes projections **546** extending axially from the shaft **544**. When the shaft **544** is positioned in the linkage aperture **532**, the projections **546** extend beyond the frame **522** and are received in slots **556** in alignment indicator **550** for keying the orientation of the alignment indicator **550** with the alignment of the crossbar linkage **540**, and hence with the alignment of the crossbar apparatus **440** and the pattern apparatus **430**. The alignment indicator **550** includes an alignment arrow **552** for indicating alignment on a scale that may be set forth on the positioning body **520**. An indicator pin **558** having a shaft **559** may be employed to pin the alignment indicator **550** to the crossbar linkage **540**.

Attachable to the bottom **526** of the positioning body **520** is skid **560**. The skid **560** includes skid apertures **562**, one of which may include an aperture flat **564** for ensuring proper alignment and positioning of the skid **560** with respect to the positioning body **520**. The skid **560** is attached to the bottom **526** of the positioning body **520** by means of skid bolts **566** having threaded shafts **568** which co-act with threaded apertures in the bottom **526** of the positioning body **520**. Of course, the skids could be formed integrally as part of the positioning body.

The sides **524** of the positioning body **520** include slots **570** extending in a facing relationship along the sides **524**. The slots extend from exterior surfaces of the sides to interior surfaces thereof, i.e., to the interior rectangular aperture formed within the positioning body **520**.

Alignment Apparatus

The alignment apparatus **580** interconnects with the positioning body **520** by means of alignment guide body **582** which is a U-shaped member having sides **584** and a bottom **586**. The alignment guide body **582** is sized to fit within the rectangular aperture formed within the positioning body **520**. The alignment guide body **582** is retained within the positioning body by means of guide studs **572** that extend through the sides **524** of the positioning body **520** within the slots **570** and into guide apertures **588** at one side of the alignment guide body **582**. At the other side of the alignment guide body **582** a lock stud **584** extends through the slot **570** in the side **524** of the positioning body **520** and into a threaded lock aperture **589** in the alignment guide body **582**. The guide studs **572** and the lock stud **574** co-act to maintain the alignment guide body **582** within the positioning body **520**, and the lock stud **574** can be threaded down to lock the vertical position of the alignment guide body **582** with respect to the positioning body **520**.

At upper ends **590** of the sides **584** of the alignment guide body **582** are plate apertures **591**. The alignment plate **592** includes bolt apertures **595** aligned with the plate apertures **591** of the alignment guide body **582**, and plate bolts **594** extend through the bolt apertures **595** in the alignment plate **592** and into the plate apertures **591** to secure the alignment plate **592** to the alignment guide body **582**. The alignment plate **592** further includes rod guide aperture **597** which receives rod guide bolt **596** therethrough to interconnect the alignment plate **592** with the IM rod guide **610** as will hereinafter be described. Additionally, the alignment plate **592** includes lock slot **606** extending through the alignment plate **592** along an arc for purposes hereinafter described.

The IM rod guide **610** includes IM rod aperture **612** for receiving an IM rod therethrough. The IM rod guide **610** is interconnected at a forward end with the alignment plate **592** by means of plate attachment aperture **614** on the rod guide **610** which receives rod guide bolt **596** therein, after such bolt **596** passes through the alignment plate **592** to secure the rod guide **610** in a pivoting relationship with respect the alignment plate **592** at forward ends of the rod guide **610** and the alignment plate **592**. The IM rod guide **610** is additionally interconnected with the alignment plate **592** by rod guide lock bolt **600** which includes a threaded shaft **210** and

pin aperture **602**. The rod guide lock bolt **600** extends through the slot **606** in the alignment plate **592** and through threaded lock bolt aperture **616** in the rod guide **610** where it is captured by means of capture pin **618** extending through the pin aperture **602**. The IM rod guide further includes rod guide handle **620** which is configured to be easily manipulated.

The alignment plate **592** further includes a printed angular rotation scale which indicates the degree of angular rotation between the rod guide **620** and the alignment apparatus, and hence, the angular rotation between the IM rod and the positioning body **520**. After such alignment is determined, it can be locked into place by tightening down rod guide lock bolt **600**. Thereafter, with such angular rotation fixed, the pattern apparatus **430** can be positioned with respect to the bone to cut, and the positioning apparatus **510** can be removed from interconnection with the IM rod and the pattern apparatus **430**, the IM rod removed from the bone, and bone cutting can be initiated.

In another embodiment, as shown in FIGS. **28**A, **28**B, **28**C and **28**D, IM rod guide block **630** is used instead of the alignment plate **592** and the alignment guide body **582**. The IM rod guide block **630** includes a rear surface **632**, a front surface **634**, a top surface **636** and sides **638**. The sides **638** include retaining flanges **640** at the rear and front surfaces for retaining the IM rod guide block **630** within the rectangular aperture formed by the positioning body **520**. The IM rod guide block **630** further includes IM rod aperture **642** extending through the block **630** from the rear surface **632** to the front surface **634** for accepting the IM rod therethrough. The rod aperture **642** extends through the guide block **630** at an angle A with respect to axis of the guide block for accommodating the varus/valgus orientation of the femur. The guide block **630** is part of a set of blocks having rod apertures of various angles extending therethrough, i.e., 5, 7, 9, 11, 13 degrees, for use with femurs having varying angles of orientation. The guide block **630** also includes lock aperture **646** for locking the proper vertical position of the guide block **630** with respect to the positioning body **620**. The guide block **630** may additionally include two apertures **644** for accepting an anterior referencing arm for use in determining the anterior/posterior size of the femur. It should be noted that other alignment means for aligning the positioning apparatus with respect to a bone to be cut are considered within the scope of the present invention.

Fixation Means

Various fixation means, including those known in the art, can be used to fix the pattern plate or plates to the femur or other bone to be cut. FIG. **29** shows a preferred fixation means, generally indicated at **660**. The fixation means **660** includes a spike plate **664** carrying on one side thereof a spike or spikes **662** for contacting, and even extending into, bone **661**. At the other side of the spike plate **664** is spike plate socket **666** for receiving plate driving ball **668** in a keyed relationship therewith. The driving ball **668** is interconnected to an end of driving sleeve **670** and which has a threaded aperture extending therein from the opposite end thereof.

A driving screw **672** having a threaded shaft **674** co-acts with the internally threaded driving sleeve **670** such that the rotation of the driving screw **672** either propels or retracts the driving sleeve **670**, as well as the spike or spikes **662**, with respect to the driving screw **672**. The driving screw **672** further includes a captured head **678** and capture flange **676**. The captured head **678** is received within a fixation aperture **434** in the pattern plate **432**, the capture flange **676** preventing the captured head **678** from passing through the fixation aperture **434**. A driving cap **680** is interconnected with the captured head **678** at the outside of the pattern plate **432**. The driving cap **680** includes a shaft **682** received by the captured head **678**, a flanged head **684** for contacting against the outside of the pattern plate **432**, and a driver recess **686** of any desirable configuration for receiving driving means such as a flat, phillips or hex head driving means for driving the driving cap **680** to drive the driving screw **672** to move the spike or spikes **662** towards or away from a bone.

Importantly, this type of fixation means allows for fixation of the pattern plates **432** to even osteoporotic bones. Additionally, this fixation means is self-adjusting to fit changing contours of bones. Further, because of its relatively low profile, this fixation means does not interfere with soft tissue about a bone to be cut. Other types of fixation means include cannulated screws, pins, spring loaded screws, captured screws, spiked screws and/or combinations thereof, all of which are considered within the scope of the present invention and could be used in connection with the present invention.

Anterior/Posterior Referencing

The apparatus of the present invention further includes built-in anterior/posterior referencing means as shown in FIG. **30** for use in connection with preparation of the distal femur in total knee replacement. As is known in the art, anterior/posterior referencing refers to proper positioning of the distal femur cuts with respect to the anterior and/or posterior sides of the femur or other bone to be cut.

The anterior/posterior difference between femoral implant sizes may vary by as much as 3 to 5 millimeters between sizes. Of course, many femurs are between sizes. Disregarding proper positioning of the cutting guide and the associated femur cuts could lead to flexion contracture (where the bone is slightly below size and the implant adds too much material to posterior side of femur which results in the inability to move the knee into flexion because the extra posterior material contacts the tibial implant components) and/or anterior notching of the femur (where the bone is slightly above size and the anterior runout point of the anterior cut is recessed in the anterior side of the bone in a sharp notch, thus seriously weakening the structural integrity of the distal femur, especially under cyclic fatigue or impact loading conditions).

Anterior referencing systems have a major advantage over posterior referencing systems in that they theoretically never notch the anterior cortex of the femur. The drawback of anterior referencing is that a slightly larger bone results in collateral ligament laxity in flexion and a slightly smaller bone will result in collateral ligament tightening in flexion (flexion contracture).

Posterior referencing systems have a major advantage over anterior referencing systems in that they theoretically never develop flexion contracture. The drawback is that a slightly large femur is prone to anterior notching, which can increase the likelihood of distal femoral fractures under either impact loading or cyclic fatigue loading.

Another approach to anterior/posterior referencing is a hybrid design that allows for both anterior and posterior referencing. The positioning apparatus **510** references the posterior femoral condyles (posterior referencing), while the pattern plates **432** allow for precise referencing of the anterior femoral cortex. The anterior referencing device can be as simple as that shown in FIG. **30**, wherein a referencing pin **694** is placed through the anterior-most cutting paths **436** of the pattern plates **432** to contact the anterior femoral cortex **661**. The pattern plates **432** include markings S (smaller size) and L (larger size). When the pin **694** falls

between the S and L marks, the pattern plates **432** are the proper size and are properly positioned for that femur. If the pin **694** falls outside the range marked by S and L towards the S side, a smaller size pattern plate should be used, and conversely, if the pin **694** falls outside the range on the L side, a larger size pattern plate should be used. Alternatively, the pattern plate **432** could be adjusted vertically via means not shown to compensate for between-size bones.

In another embodiment, the pattern plate could include a plunger assembly at the anterior end of the cutting path. The plunger could be movable vertically to contact the femur and indicate size of the femur with respect to the pattern plate in use. As such, the plunger could be incrementally marked from +4 to −4 millimeters with 0 being the proper size for the pattern plates in use. Again, the pattern plates could be sized up or down if the femur is off of the scale, or the pattern plates could be moved up or down to compensate for between size bones depending upon surgeon preference. If, for example, a bone registers a +2, anterior notching of the femur would occur. To avoid this, the pattern plates could be moved anteriorally 1 millimeter to +1. In this manner, anterior notching would be minimized and the posterior femoral condyles would only lack 1 millimeter of material, which should not be detrimental as some ligamentous laxity in flexion is acceptable because the collateral ligaments are normally slightly looser in flexion than they are in extension. It should be noted that the radii or curve in the anterior-most area of the cutting path will assure that anterior notching is easily avoidable.

Pattern Plate with Tracking Means

Another embodiment of the pattern plates of the present invention is shown in FIG. **31**. In this embodiment, the pattern plates, generally indicated at **710**, basically comprise only the lower edge, or bearing surface **716** of the cutting path **436** of pattern plates **432** shown in FIGS. **19-21**. Accordingly, the pattern plate **710** includes fixation apertures **712** and crossbar aperture **714**. The milling apparatus bears against the bearing surface and follows the same therealong to resect the bone in accordance with the shape of the bearing surface **716**. Of course, the bearing surface could be smaller or larger than the desired cut location depending on the size of the milling apparatus. The pattern plate **710** could further include a groove or guide means **718** extending in the pattern plate alongside the bearing surface and the milling apparatus could include an arm or other retaining linkage **717** extending from the handle or bushing of the milling apparatus and into the groove **718** for engagement with the groove **718** for guiding or retaining the milling apparatus along the bearing surface **716** of the pattern plate **710**. Alternatively, it should be noted that the bearing surface could also comprise just the upper surface of the cutting path **436** of the pattern plates **432**, as shown in FIGS. **19-21**.

Ligament Balancing

As shown in FIG. **32**, an alternative embodiment of the alignment guide body **730** can be used for performing ligament balancing. The alignment guide body **730** of this embodiment can include a skid **732** formed as a part of the guide body **730**, or attachable thereto. The skid **732** is of a relatively thick cross-section, approaching or equal to the cross-section of the guide body **730**. The guide body **730** is attached to the femur **661** and the femur may be moved from extension to flexion and back, while the ligament tension of the collateral ligaments is reviewed. Ligamentous release can be performed to balance the ligaments. Further, shims **736**, in either a rectangular cross-section (FIG. **32**A) or an angled cross-section (FIG. **32**B), can be used in connection with the alignment guide body **830** and skid **732**. These shims could be positioned between the underside of the skid **732** and the resected tibia.

Milling Means

In a preferred embodiment of the invention, a cylindrical milling bit is used for following the cutting path described in the pattern plates for resecting a bone. Importantly, it is within the scope of the present invention to use a flat reciprocating bit, much like a hacksaw, for following the cutting paths described in the pattern plates for resecting a bone.

Further, it may be desirable to make all or some of the cuts using a cylindrical milling bit or a flat reciprocating bit having a smooth center section without cutting means. An advantage of a cutting tool without cutting means along a center portion thereof is the protection of posterior cruciate ligament during resection of the femur. Accordingly, one cutting tool could be used to make the anterior cut, the anterior chamfer, the distal cut and the posterior chamfer, while another cutting tool, with a smooth center portion, could be used to make the posterior cut to avoid any chance of jeopardizing the posterior cruciate ligament.

Additionally, the milling bits herein described can be used with or without a guide handle as will hereinafter be described. Further, it should be pointed out that it is within the scope of the present invention to fabricate the milling bit or other cutting tool from metal as heretofore known, or to alternatively fabricate the milling bit or other cutting tool from a ceramic material. An advantage of a ceramic milling bit or cutting tool is that such resists wear and, accordingly would be a non-disposable component of the present invention which would help to reduce the cost of the system of the present invention.

Three Dimensional Shaping

Initially, it should be noted that the term cutting profile the profile geometry of a mediolateral section taken normal to the cutting path through the bony surfaces created by cutting the bone. As shown in FIG. **33**, in an alternate embodiment of the present invention, a milling apparatus having a three-dimensional profile, or a form cutter, can be used to shape a bone in three-dimensions. The curved profile milling bit **750**, like the milling bits used in the previous embodiments of the present invention, includes cutting teeth **752** along the length thereof and spindles **754** at the ends thereof. This milling bit **730** can follow a pattern described by pattern plates and can be guided with a handle as will be hereinafter described.

Importantly, by using a milling bit having a curved profile, one can cut a femur to resemble the natural shape of the femur, i.e., the resected femur would include condylar bulges and a central notch. This would reduce the amount of bony material that must be removed from the femur while maintaining the structural integrity of the femur. Of course, any prosthetic implant used for attachment to a femur resected by the curved profile milling bit would necessarily have an appropriately contoured inner fixation surface for mating with contoured surface of the femur. Additionally, it should be noted that the curved profile milling bit could have one or more curvilinear bulges along the length thereof, as shown in FIG. **33**, or alternatively, could have one or more bulges discretely formed along the length thereof as shown in FIG. **35**.

Guide Handle

As shown in FIG. **34**, a guide handle, generally indicated at **698** may be used to guide the milling bit along the cutting path of the pattern plate. The guide handle **698** comprises a grip portion **700** which is grasped by the user for manipu-

lating the guide handle **698** and accordingly, the milling bit. The grip portion **700** is interconnected with a crossbar member **702** which includes a extension member **703** telescopically interconnected therewith. The crossbar member **702** and the extension member **703** may be positioned perpendicular with respect to grip portion **700**. The extension member **703** is telescopically movable in and out of crossbar member **702**. Means may be provided for locking the relative position of the extension with respect to the crossbar. Also, it should be noted that the grip portion may rigidly or pivotally be interconnected with the crossbar as desired.

Extending from outer ends of the crossbar **702** and the extension member **703** are sidebars **704** in facing and parallel relationship. The sidebars **704** have two ends, the first of which are interconnected with the crossbar and the extension member, and the second of which are configured to receive and capture spindles or bushings of a milling bit in spindle bushings **706**. The spindle bushings are positioned in a facing relation and could include captured bushings. The captured bushings receive the spindles of a milling bit. The captured bushings are sized to be received by the cutting path in the pattern plates and co-act therewith to guide a milling bit therealong. Accordingly, after the pattern plate or plates are attached to a bone, the milling bit is placed into the cutting path. Next a milling handle **698** is positioned such the spindle bushings are aligned with the spindles of the milling bit. Next, the extension is actuated to retract into the crossbar to move the spindle bushings onto the spindles of the milling bit where they are captured. Next, the spindle bushings are positioned within the cutting path of a pattern plate or plates. If necessary, the extension and crossbar can be locked down to lock the entire apparatus. Next, the milling bit is actuated and the grip portion of the handle is grasped and manipulated to move the milling bit along the cutting path to cut a bone.

Distally Positioned Pattern Plate

As shown in FIGS. **35-37**, in an alternate embodiment of the present invention for resecting a femur, the plates could take the form of a rail assembly, generally indicated at **760**, positioned distally of the distal femur **661**. The plates could be affixed to the femur by fixation arms **762**, attached at one or more points to the rail assembly **760**, and including fixation apertures **764** for receiving fixation screws or other fixation means for attaching the fixation arms **762**, and hence the rail assembly **760**, to a distal femur **661**. The rail assembly **760** includes one or more guide rails **766** which match the shape of the desired resection, though the rails may be larger or smaller depending on the dimensions of the milling apparatus used and the positioning of the assembly **760** with respect to the femur. In the case that the assembly **760** includes two guide rails **766**, as shown, an end rail **768** may be used to interconnect such guide rails **766**. The end rail **768** could be replaced by a connection means similar to the crossbar apparatus **440**, hereinbefore described. The rail assembly may be positioned on the distal femur in accordance with the teachings contained herein, or in any other manner known in the art. After alignment, according to any means disclosed herein or known or developed, and after fixation of the assembly to a femur, a milling bit **770** may be used to follow the guide rails **766** to resect the femur **661**, the guide spindles **772**, or bushings (not shown), of the milling bit **770**, contacting and riding the guide rails **766**. Importantly, the rail assembly **760** is attached to a femur and used in much the same way as the pattern plates previously described with the exception that the rail assembly can be positioned substantially distal of the femur, thereby potentially requiring less exposure and possibly resulting in less interference for placement thereof. The rail assembly **760** could further include an upper retaining rail for forming a slot or cutting path for capturing the milling bit therein. Additionally, it should be noted that any milling bit described herein could be used with rail assembly **760** including a curved profile milling bit.

Curvilinear Implants

As shown in FIGS. **38** and **39**, an implant **780** may have curvilinear interior surfaces **782**, as well as a more conventional curvilinear exterior surface. The particular example cited herein is a femoral implant used in total knee arthroplasty but the principles described herein may be applied to any application where foreign or indigenous material is affixed to an anatomic feature. The curvilinear bone surfaces necessary for proper fixation of such an implant may be generated through the use of the curvilinear milling or form cutter and the curvilinear cutting path means discussed herein. While it is possible to use multiple form cutters with differing geometries and, therefore, an implant with an internal geometry that varies along the cutting path from the anterior to the posterior of a femur, for the sake of intraoperative time savings a single form cutter is preferable.

The mediolateral cross-sectional internal geometry of such an implant, and therefore the necessary resected bony surfaces of the femur, are consistent about the cutting path in a single form cutter system. It should be noted that the implant may possess a notch between members **784** (posterior femoral implant condyles) in the areas approximately in between the distal and posterior femoral condylar areas to accommodate the posterior cruciate ligament and other factors. Because of the notch between the posterior femoral condyles it may not be necessary for the form cutter to cut any material in the notch. It may be desirable to provide outer flat surfaces **785** with an adjoining curvilinear surface **782** positioned therebetween. Other combinations of flat or curvilinear surfaces are also within the scope of the present invention.

Additionally, it may be advantageous to utilize a secondary form cutter as shown in FIG. **47** for use in creating a slot or slots in or near the distal area of the femur after it has been resected. Such a secondary cutter **790** would include engagement means **792** for engagement with driving means, and a shaft **794** carrying cutters **796** for cutting slots into the femur through one or more of the resected surfaces thereof. Through the inclusion of an additional or adjunct cutting path in the pattern means, it would be advantageous to utilize the form cutter to create the aforementioned slots to accommodate the fixation fins which may be molded as an integral part of the interior surface of the implant. These fins would provide mediolateral fixation stability in addition to that provided by the trochlear groove geometry of the implant. Further, the fins also provide for additional surface area for bony contact and ingrowth to increase implant fixation both in cemented and cementless total knee arthroplasty.

There are numerous advantages to the femoral component herein described. Foremost, it will allow for the thinnest implant cross-section possible (perhaps 3 mm to 6 mm in thickness) and therefore necessitate the removal of the least amount of viable osseous tissue. This is especially critical in situations where the probability of revision surgery is high and the amount of viable bone available for revision implant fixation and apposition is a significant factor in the viability of the revision procedure. Since the form cutter configuration allows for similar amounts of tissue to be removed from the trochlear groove, the bony prominences surrounding the

trochlear groove, the femoral condyles, and the other articular surfaces of the femur, the external geometry of the femoral implant can be optimized for patellofemoral articulation as well as tibiofemoral articulation. In essence, the kinematics of the artificial joint could be made to be as close as possible to that of a healthy, natural knee joint. In addition, the curvilinear geometry of the implant dramatically decreases the stress risers inherent in conventional rectilinear femoral implants and allows for a thinner cross-sectional geometry while potentially increasing the resistance of the implant to mechanical failure under fatigue or impact loading. Conversely, the curvilinear geometry of the implant may also allow for an advantageous reduction in the flexural rigidity of the implant which may result in avoidance of the "stress-shielding" inherent in rigid implant designs. Stress shielding being a phenomenon that may occur when living bony tissue is prevented from experiencing the stresses necessary to stimulate its growth by the presence of a stiff implant. This phenomenon is analogous to the atrophy of muscle tissue when the muscle is not used, i.e., when a cast is placed on a person's arm the muscles in that arm gradually weaken for lack of use.

Additionally, the curvilinear implant design may allow for the use of a ceramic material in its construction. Since ceramics are generally relatively weak in tension, existing ceramic implant designs contain very thick cross-sections which require a great deal of bony material removal to allow for proper implantation. Utilization of ceramics in the curvilinear implant will not only allow for the superior surface properties of ceramic, but also avoid the excessively thick cross-sections currently required for the use of the material.

This could result in a less expensive femoral implant because of the reduced amount of material needed for the implant, as well as an improved, more natural, and even stronger knee replacement. It may be desirable to vary the cross-section of the implant **780** to assist in seating the implant and to increase the strength and fit of the implant. The implants of the present invention having curvilinear implant surfaces could be fabricated of metal, plastic, or ceramic or any other material. Further, the thickness of the implants and the material required to fabricate the implant could be reduced as the implants are adapted to increasingly curvilinear surfaces. Also, it should be pointed out the such implants with curvilinear implant surfaces require less bone to be removed to obtain a fit between the implant and the bone. Finally, it should be noted that curvilinear milling bits hereinbefore described would work well for preparing a bone to receive an implant with curvilinear interior implant surface.

Patella Shaping

The apparatus for preparing a patella, as shown in FIGS. **40-42**, comprises a plier-like patella resection apparatus generally indicated at **800**. The patella resection apparatus **800** includes grip handles **802** for manipulating the apparatus, cross-over members **804** pivotally interconnected with each other by pin **806**, and patella clamp members **808** extending from the cross-over members in parallel and facing relation. The patella clamp members **808** have beveled edges **810** for contacting and supporting a patella along the outer edges thereof. Guide member structures **812** are mounted on each of the patella clamp members **808** to form a retainer for a cutting means to follow a cutting path defined by the upper surface of the clamp members. Bushings **814** are captured within the retainer and the cutting path for receiving a cutting means **816** and guiding the cutting means **816** along the cutting path.

In preparing the patella, the pattern device may be an integral part of the positioning apparatus which is oriented and located by referencing the geometry of the patella itself as well as the structures of the patellofemoral mechanism to determine the location and orientation of a predominantly planar resection. The cutting device may then be employed to perform the resection of the patella by traversing the path dictated by the pattern device, thus dictating the final location and orientation of the patella prosthesis.

Bone Substitution and Shaping

Referring now to FIG. **43**, another embodiment of the pattern apparatus of the present invention for cutting bone is shown. This embodiment of the invention includes pattern plates **832** having cutting paths **836** described therein. The pattern plates **832** may be positioned on a bone **828** having a tumor or other pathology **829** associated therewith. The pattern plates **832** may be interconnected by crossbars **838** with opposing pattern plates (not shown) positioned on the opposite side of the bone **828**. Further, each set of pattern plates **832** could be interconnected by means of positioning rod **839** extending between the crossbars **838** to maintain the relative location and orientation between the sets of pattern plates **832**. The pattern plates can be positioned along the bone in accordance with what is known in the art, disclosed herein or hereafter developed. After the pattern plates are properly positioned, they can be affixed to the bone **828** with fixation means extending through fixation apertures **834**. After the pattern plates are properly located and affixed to the bone, cutting can commence by traversing a cutting means along the cutting paths **836** of the pattern plates **832**. By this step, the tumor or other pathology **829** can be cut from the bone **828** and a bone graft or other surgical procedure can be implemented to repair and/or replace the bone that has been cut. The benefits of cutting a bone with the pattern plates of the present invention include providing smooth and even cuts to the bone to facilitate fixation of bone grafts or other means for repairing and/or replacing bone. Further, the same pattern plates can be used to cut another identical sized and shaped bone for grafting to the first bone to replace the cut away bone.

Alternate Positioning and Alignment Guide

An alternate positioning and alignment guide is generally indicated at **840** in FIG. **44**. The positioning body **840** comprises a crossbar linkage **842** and an alignment indicator **844** at an upper end thereof for interconnecting with a crossbar to align pattern plates interconnected with such crossbar. The positioning body **840** also includes an alignment block **846** for interconnecting with an intramedullary rod in much the same manner as the IM rod guide block shown in FIG. **28**. The alignment block **846** is vertically movable along the positioning body **840** and can be locked into a desired position by means of lock screw **860** which bears against a flange **848** of the alignment block **846**. The positioning body **840** further includes skids **850** for contacting the posterior surface of the distal femoral condyles for referencing same.

Unicondylar and/or Single Pattern Plate Support

As shown in FIGS. **45** and **46**, one pattern plate of the present invention can be used by itself to guide a cutting means along a cutting path to cut a bone. Such an application is particularly useful for unicondylar resecting of a femur. Use of a single pattern plate **862** is facilitated by bushing **868** having an outer flange **870** with a bearing surface **872** and an internal bore **874** sized to receive a spindle **865** of a cutting tool therein. The bushing **868** is sized to fit into the cutting path **864** of the pattern plate **862**, the bearing surface **872** of the flange **870** contacting the side of the pattern plate

862. Washer 876 includes a central bore 878 sized to receive the far end of the bushing 868 extending past the pattern plate 862, the washer bearing against the side of the pattern plate 862 opposite the side that the bearing surface 872 of the flange 870 of the bushing 868 bears against. Thus, the washer and the bushing co-act to form a stable link with a pattern plate. As shown in FIG. 46, this link can be fortified by means of bearing arms 880 interconnected with the bushing and the washer, or formed integrally as part thereof, which by pressure means are forced together to retain the bushing within the cutting path of the pattern plate. After the bushing is captured within the cutting path, the spindle of the cutting means can be inserted through the bushing and interconnected with means 866 for driving the cutting means. Alternatively, it should be pointed out that when using a single pattern plate to cut a bone, it may be desirable to support the cutting means at the pattern plate and also at the other end thereof. One could effect such desired support at the other end of the cutting means by a brace or other linkage interconnecting the other end of the cutting means with a secondary support or anchor means positioned on the opposite side of the bone or at another location.

Revisions

Conventional revisions require removal of the old implant and the referencing of uncertain landmarks. Revisions, by means of the present invention, allow for reference of the implant while it is still on the bone. One can obtain varus/valgus referencing, distal resection depth, posterior resection depth and rotational alignment by referencing the geometry of the implant with the alignment guide. An extramedullary alignment rod can be used to facilitate flexion/extension alignment. The fixation screws can then be advanced to touch the bone and mark their location by passing standard drill bits or pins through the cannulations in the fixation screws and into the bone. Then, the pattern and guide device are removed, the old implant removed, and the pattern device repositioned by means of the marked location of the fixation screws and then fixed into place. Accordingly, the cuts for the new implant, and thus the new implant itself, are located and orientated based off of the old implant. This results in increased precision and awareness of the final implant location and orientation as well as potential intraoperative time savings.

The particular example of the present invention discussed herein relates to a prosthetic implant for attachment to a femur in the context of total knee arthroplasty, i.e., a femoral implant. However, it should be pointed out that the principles described herein may be applied to any other applications where foreign or indigenous material is affixed to any other anatomic feature.

As shown generally in FIGS. 38 and 48, the implant apparatus of the present invention, generally indicated at 910, comprises curvilinear interior fixation surface 920 as well as curvilinear exterior bearing surface 940. Importantly, the implant of the present invention includes curvilinear surfaces extending from an anterior to a posterior area of the femur and/or implant, as is conventionally known, as well as curvilinear surfaces extending from a medial to a lateral area of the femur and/or implant to approximate the shape of natural femur. In other words, the fixation path (i.e., corresponding to the cutting path along which the milling bit rides to resect the femur; indicated by arrow A in FIG. 38) as well as the fixation profile (as one proceeds along the cutting profile orthogonally to the cutting path; indicated by arrow B in FIG. 38) are both predominantly curvilinear. As such, the cutting profile (arrow B) of the interior fixation surface 920 could include a curved or flat area 922 and another curved or flat area 924 therebetween. Preferably, the outer areas 922 are flat or relatively flat and the inner area 924 is curved to approximate the shape of a natural distal femur 912. It should be pointed out that the outer areas 922 could be curved, and the inner area 924 could also be curved, but embodying differing radii of curvature. Additionally, it should be pointed out that the geometry of the internal fixation surface 920 of the implant 910 could be varied as desired. As such, any combination of flat surfaces and curvilinear surfaces could be used. As shown in FIG. 48, and in more detail in FIGS. 48A, 48B, 48C and 48D, the cross-sectional thickness and mediolateral width of the implant of the present invention could vary along the implant 910. This variance results from merging a cutting tool to cut a bone, i.e., the implant 910 closely resembles in size and shape the material removed from the bone. Accordingly, the cut starts as a point 925 and grows in depth and width.

The curvilinear bone surfaces necessary for proper fixation of such an implant 910 may be generated through the use of the curvilinear milling bit or form cutter and the curvilinear cutting path means discussed in the previous related applications set forth herein, the entire disclosures of which are expressly incorporated herein by reference. Basically, the milling bit has a profile resulting in form cutter configuration which is concentric about its longitudinal axis to effect a curvilinear cutting profile for receiving the implant of the present invention. One embodiment of such a form cutter is shown in FIGS. 35 and 49. While it is possible to use multiple form cutters with differing geometries and therefore an implant 910 with an internal geometry that varies along the cutting path from the anterior to the posterior of a femur, for the sake of intraoperative time savings, a single anatomically optimal form cutter is preferable.

The form cutter shown in FIGS. 35 and 49 comprises a cutting guide 950 having cutting paths 952 interconnected by member 954. A milling bit 960 having cylindrical milling areas 962 at the ends, and a curved milling area 964 at the center could be used. Of course, the milling areas carry cutting teeth. Spindles 961 interconnected at each end of the milling bit 960 could engage and ride the cutting path 952 of the cutting guide 950. The milling bit 960 is then guided along the cutting path 952 by means of a handle. Importantly, the shape of the milling bit 960 could be varied as desired to create a resection having a desired cutting path as well as a desired cutting profile.

The mediolateral cross-sectional internal geometry of such an implant 910, and therefore the necessary resected bony surfaces of the femur, are consistent about the cutting path in a single form cutter system. It should be noted that the implant 910 may possess a notch 970 between members 972 (posterior femoral implant condyles) in the areas approximately between the distal and posterior femoral condylar areas to accommodate the posterior cruciate ligament, as well as for other reasons. Because of the notch 970 between the posterior femoral condyles, the form cutter may not cut any material in the notch 970.

Additionally, it may be advantageous to utilize a secondary form cutter as shown in FIG. 47 for use in creating a slot or slots in or near the distal area of the femur before or after it has been resected. Such a secondary cutter 790 would include engagement means 792 for engagement with driving means, and a shaft 794 carrying one or more cutters 796 for cutting slots into the femur through one or more of the resected surfaces thereof.

Through the inclusion of an additional or adjunct cutting path in the pattern means, it would be advantageous to utilize the form cutter to create the aforementioned slots in the distal femur to accommodate the fixation fins which may be molded as an integral part of the interior surface of the implant **910**. An implant with fixation fins is shown in FIG. **50**. The fins **980** would provide mediolateral fixation stability in addition to that provided by the trochlear groove geometry of the implant **910**. Further, the fins also provide for additional surface area for bony contact and ingrowth to increase implant fixation both in cemented and cementless total knee arthroplasty.

FIG. **33***b* shows another embodiment of a milling bit, generally indicated at **754** for creating a curvilinear cutting path and curvilinear cutting profile in femur **756**. In this embodiment, the transition from a first cutting area **984** to a second cutting area **986** is continuous and smooth. This milling bit **754** also includes spindles **981** at the ends thereof for engagement with pattern means to guide the milling bit along a cutting path.

There are numerous advantages to the femoral component herein described. Foremost, it will allow for the thinnest implant cross-section possible (perhaps 3 mm to 6 mm in nominal thickness) and therefore necessitate the removal of the least amount of viable osseous tissue. This is especially critical in situations where the probability of revision surgery is high and the amount of viable bone available for revision implant fixation and apposition is a significant factor in the viability of the revision procedure. Since the form cutter configuration allows for similar amounts of tissue to be removed from the trochlear groove, the bony prominences surrounding the trochlear groove, the femoral condyles, and the other articular surfaces of the femur, the external geometry of the femoral implant can be optimized for patellofemoral articulation as well as tibiofemoral articulation. In essence, the kinematics of the artificial joint could be made to be as close as possible to that of a healthy, natural knee joint.

In addition, the curvilinear geometry of the implant dramatically decreases the stress risers inherent in conventional rectilinear femoral implants and allows for a thinner cross-sectional geometry while potentially increasing the resistance of the implant to mechanical failure under fatigue or impact loading. The implant could have a relatively consistent cross-sectional thickness throughout the implant, or it could be varied as desired.

The curvilinear geometry of the implant may also allow for an advantageous reduction in the flexural rigidity of the implant which may result in avoidance of the "stress-shielding" inherent in rigid implant designs. Stress shielding being a phenomenon that may occur when living bony tissue is prevented from experiencing the stresses necessary to stimulate its growth by the presence of a stiff implant. This phenomenon is analogous to the atrophy of muscle tissue when the muscle is not used, i.e., when a cast is placed on a person's arm the muscles in that arm gradually weaken for lack of use.

Further, the curvilinear implant of the present invention could allow for the use of a ceramic material in its construction. Since ceramics are generally relatively weak in tension, existing ceramic implant designs contain very thick cross-sections which require a great deal of bony material removal to allow for proper implantation. Utilization of ceramics in the curvilinear implant would not only allow for the superior surface properties of ceramic, but also avoid the excessively thick cross-sections currently required for the use of the material.

The curvilinear implant of the present invention could result in a less expensive femoral implant because of the reduced amount of material needed for the implant, as well as an improved, more natural, and even stronger knee replacement. It may desirable to vary the cross-section of the implant to assist in seating the implant, to increase the joint kinematics and to increase the strength and fit of the implant. The implant of the present invention could be fabricated of metal, plastic, or ceramic or any other material or combination thereof. Further, the thickness of the implants and the material required to fabricate the implant could be reduced as the implants are adapted to increasingly curvilinear surfaces. Also, it should be pointed out that such implants with curvilinear implant surfaces require less bone to be removed to obtain a fit between the implant and the bone. Finally, it should be noted that curvilinear milling bits hereinbefore described would work well for preparing a bone to receive an implant with curvilinear interior implant surface.

Importantly, by using a milling bit having a curved profile, one can cut a femur to resemble the natural shape of the femur, i.e., the resected femur would include condylar bulges and a central notch. This would reduce the amount of bony material that must be removed from the femur while maintaining the structural integrity of the femur. Of course, any prosthetic implant used for attachment to a femur resected by the curved profile milling bit would necessarily have an appropriately contoured inner fixation surface for mating with contoured surface of the femur. Additionally, it should be noted that the curved profile milling bit could have one or more curvilinear bulges along the length thereof, as shown in FIGS. **35** and **49**, or alternatively, could have one or more bulges discretely formed along the length thereof.

The complete disclosures of the patents, patent applications and publications cited herein are incorporated by reference in their entirety as if each were individually incorporated. Various modifications and alterations to this invention will become apparent to those skilled in the art without departing from the scope and spirit of this invention. It should be understood that this invention is not intended to be unduly limited by the illustrative embodiments and examples set forth herein and that such examples and embodiments are presented by way of example only with the scope of the invention intended to be limited only by the claims set forth herein.

What is claimed:

1. A method for a knee arthroplasty procedure comprising:

positioning at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface on the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direction along the long axis of the saw

blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting a knee arthroplasty implant on the at least one resected surface.

2. The method of claim **1** wherein the long bone is the femur and the step of positioning the at least one planar guide surface is performed proximate a distal end of the femur.

3. The method of claim **2** wherein the step of using the cutting tool creates at least two resected surfaces, including a distal surface on the femur and an anterior surface on the femur.

4. The method of claim **1** wherein the long bone is a tibia and the step of positioning the at least one planar cutting guide surface is performed proximate a proximal end of the tibia.

5. A method for a knee implant procedure comprising:

positioning at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface proximate the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direction along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting a knee implant on the at least one resected surface,

wherein the at least one guide surface includes at least two portions, the portion located along the at least one of the medial side or the lateral side and an other portion located along an anterior side and proximate the end of the long bone and having a longer dimension generally along the at least anterior side and a shorter dimension generally transverse to the longer dimension, wherein the step of positioning the at least one guide surface is performed such the other portion extends to less than about one-half of a width of the anterior side.

6. A method for a knee implant procedure comprising:

operably positioning at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is operably positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being operably positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side orthe lateral side and a shorter dimension generally transverse to the longer dimension;

using an alignment mechanism operably coupled to the at least one planar cutting guide surface to align the at least one guide surface relative to the long bone in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment mechanism to position the at least one guide surface in a desired location and orientation;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface proximate the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direction along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting a knee implant on the at least one resected surface.

7. The method of claim **6** wherein the step of using the alignment mechanism is performed by moving the at least one guide surface through at least a portion of an infinitely adjustable range of motion for the at least one of the at least three degrees of freedom.

8. The method of claim **1** wherein the step of using the cutting tool is performed with a powered saw selected from the set consisting of an oscillating saw or a reciprocating saw.

9. A method for a knee arthroplasty procedure comprising:

providing a cutting guide having a slot adapted to receive and guide a cutting tool, the cutting tool having a saw blade with at least one cutting edge at a distal end of a long axis of the saw blade;

positioning the cutting guide in a position proximate an end of one of a femur or a tibia with at least a portion of the slot facing the end of the one of the femur or the tibia from one of a medial aspect or a lateral aspect;

extending the saw blade though the slot;

cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis, the direction of the long axis being at least one of a medial to lateral direction or a lateral to medial direction to create at least a portion of at least one resected surface; and

implanting a knee arthroplasty implant on the at least one resected surface.

10. A method for a knee arthroplasty procedure comprising:

providing a cutting guide having a slot adapted to receive and guide a cutting tool, the cutting tool having a saw blade with at least one cutting edge at a distal end of a long axis of the saw blade;

positioning the cutting guide in a position proximate an end of one of a femur or a tibia with at least a portion of the slot facing the end of the one of the femur or the tibia from one of a medial aspect or a lateral aspect by:

using an alignment guide operably coupled to the cutting guide to align the slot relative to the one of the femur or the tibia in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment guide to position the cutting guide in a desired location and orientation;

extending the saw blade though the slot;

cutting the end of the one of the femur or the tibia by moving the cutting tool along the long axis in at least one of a medial to lateral direction or a lateral to medial direction to create at least one resected surface; and

implanting a knee arthroplasty implant on the at least one resected surface.

11. The method of claim 10 wherein the step of using the alignment guide moves the cutting guide though an infinitely adjustable range of motion.

12. The method of claim 9 wherein the cutting tool is a powered saw and the step of cutting is performed with the powered saw selected from the set consisting of an oscillating saw or a reciprocating saw.

13. A method for a knee implant procedure comprising:

providing implants and instrumentation for the knee implant procedure, the implants and instrumentation including at least:

a femoral implant;

a tibial implant;

a femoral intramedullary rod;

a femoral alignment guide extending at an angle to the femoral intramedullary rod;

a femoral cut guide mountable to the femoral alignment guide;

a tibial extramedullary alignment guide; and

a tibial cut guide;

resecting a distal end of a femur of a knee including at least:

inserting the femoral intramedullary rod into an intramedullary canal of the femur;

positioning the femoral alignment guide so that a surface on the femoral alignment guide contacts a distal femoral condyle;

operably connecting the femoral cut guide to the femoral alignment guide and positioning the femoral cut guide to extend toward and generally along at least one of a medial side or a lateral side of the knee; and

guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade by using the femoral cut guide to create at least one resected surface on the distal end of the femur by guiding the long axis of the saw blade from the at least one of the medial side or the lateral side of the knee;

resecting a proximal end of a tibia of the knee including at least:

positioning the tibial extramedullary alignment guide;

operably connecting the tibial cut guide to the tibial extramedullary alignment guide and positioning the tibial cut guide generally adjacent at least a portion of an anterior side of the tibia and at least one of the medial side or the lateral side of the knee; and

guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade by using the tibial cut guide to create at least one resected surface on the proximal end of the tibia by guiding the long axis of the saw blade from at least one of the medial side or the lateral side of the knee; and

implanting the implants by:

positioning the femoral implant with at least one fixation surface of the femoral implant generally adjacent the at least one resected surface of the femur; and

positioning the tibial implant with at least one fixation surface of the tibial implant generally adjacent to the at least one resected surface of the tibia.

14. The method of claim 13 wherein the step of positioning the femoral cut guide comprises:

using the femoral alignment guide operably to align the femoral cut guide relative to the femur in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the femoral alignment guide to position the femoral cut guide in a desired location and orientation.

15. The method of claim 14 wherein the step of using the femoral alignment guide moves the femoral cut guide through an infinitely adjustable range of motion.

16. The method of claim 13 wherein the step of positioning the femoral cut guide positions the femoral cut guide to extend toward and generally along one of the medial side or the lateral side of the knee.

17. The method of claim 13 wherein the step of positioning the tibial cut guide comprises:

using the tibial alignment guide operably to align the tibial cut guide relative to the tibia in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the tibial alignment guide to position the tibial cut guide in a desired location and orientation.

18. The method of claim 17 wherein the step of using the tibial alignment guide moves the tibial cut guide through an infinitely adjustable range of motion.

19. The method of claim 13 wherein the step of positioning the tibial cut guide positions the tibial cut guide to extend toward and generally along one of the medial side or the lateral side of the knee.

20. The method of claim 13 wherein the cutting tool for the step of resecting the distal end of the femur is the same as the cutting tool for the step of resecting the proximal end of the tibia and is a powered saw and each step is performed with the powered saw selected from the set consisting of an oscillating saw or a reciprocating saw.

21. A method for providing instrumentation, implants and information for a knee arthroplasty procedure comprising:

providing a knee arthroplasty implant and a cutting guide having at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is adapted to be positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being adapted to be positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension; and

providing a surgeon with information on a method to perform the knee arthroplasty procedure using the cutting guide and the knee arthroplasty implant, the method including:

positioning the at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is positioned along one of the medial side or the lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of at least one resected surface on the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direc-

tion along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting the knee arthroplasty implant on the at least one resected surface.

22. A method for providing instrumentation, implants and information for a knee arthroplasty procedure comprising:

providing a knee arthroplasty implant and a cutting guide having at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is adapted to be positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being adapted to be positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension; and

providing a surgeon with information on a method to perform the knee arthroplasty procedure using the cutting guide and the knee arthroplasty implant, the method including:

positioning the at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is positioned along one of the medial side or the lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface proximate the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface moving the saw blade in a direction along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting the knee implant on the at least one resected surface,

wherein the at least one guide surface includes at least two portions, the portion located along the at least one of the medial side or the lateral side and an other portion located along an anterior side and proximate the end of the long bone and having a longer dimension generally along the at least anterior side and a shorter dimension generally transverse to the longer dimension, wherein the step of positioning the at least one guide surface is performed such the other portion extends to less than about one-half of a width of the anterior side.

23. A method for providing instrumentation, implants and information for a knee arthroplasty procedure comprising:

providing a cutting guide having at least one generally planar cutting guide surface, an alignment mechanism operably coupled to the at least one planar cutting guide surface and a knee arthroplasty implant; and

providing a surgeon with information on a method to perform the knee arthroplasty procedure using the cutting guide, the alignment mechanism and the knee arthroplasty implant, the method including:

operably positioning the at least one generally planar cutting guide surface that is adapted to interface with and guide a saw blade such that at least a portion of the at least one guide surface is operably positioned along one of a medial side or a lateral side and proximate an end of a long bone of a knee joint, the at least one guide surface also being operably positioned generally transverse to a long axis of the long bone with the portion of the at least one guide surface having a longer dimension generally along the at least one of the medial side or the lateral side and a shorter dimension generally transverse to the longer dimension;

using the alignment mechanism operably coupled to the at least one planar cutting guide surface to align the at least one guide surface relative to the long bone in at least thee degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment mechanism to position the at least one guide surface in a desired location and orientation;

using a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade to create at least a portion of one resected surface proximate the end of the long bone by guiding the saw blade with at least the portion of the at least one guide surface and moving the saw blade in a direction along the long axis of the saw blade, the direction of the long axis of the saw blade being generally parallel to the shorter dimension; and

implanting the knee implant on the at least one resected surface.

24. A method for providing instrumentation, implants and information for a knee arthroplasty procedure comprising:

providing a knee arthroplasty implant and a cutting guide having a slot adapted to receive and guide a cutting tool, the cutting tool having a saw blade with at least one cutting edge at a distal end of a long axis of the saw blade;

providing a surgeon with information on a method to perform the knee arthroplasty procedure using the cutting guide, the cutting tool and the knee arthroplasty implant, the method including:

positioning the cutting guide in a position proximate an end of one of a femur or a tibia with at least a portion of the slot facing the end of the one of the femur or the tibia from one of a medial aspect or a lateral aspect;

extending the saw blade through the slot;

cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis, the direction of the long axis being at least one of a medial to lateral direction or a lateral to medial direction to create at least a portion of at least one resected surface; and

implanting the knee arthroplasty implant on the at least one resected surface.

25. A method for providing instrumentation, implants and information for a knee arthroplasty procedure comprising:

providing a knee implant, a cutting guide having a slot adapted to receive and guide a cutting tool, the cutting tool having a saw blade with at least one cutting edge at a distal end of a long axis of the saw blade and an alignment guide operably coupled to the cutting guide;

providing a surgeon with information on a method to perform the knee arthroplasty procedure using the cutting guide, the cutting tool and the knee arthroplasty implant, the method including:

positioning the cutting guide in a position proximate an end of one of a femur or a tibia with at least a portion of the slot facing the end of the one of the femur or the tibia from one of a medial aspect or a lateral aspect by:

using the alignment guide operably coupled to the cutting guide to align the slot relative to the one of the femur or the tibia in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment guide to position the cutting guide in a desired location and orientation;

extending the saw blade though the slot;

cutting the end of the one of the femur or the tibia by moving the cutting tool along the long axis in at least one of a medial to lateral direction or a lateral to medial direction to create at least one resected surface; and

implanting the knee arthroplasty implant on the at least one resected surface.

26. A method for providing implants, instrumentation and information for a knee implant procedure comprising:

providing implants and instrumentation for the knee implant procedure, the implants and instrumentation including at least:

a femoral implant;

a tibial implant;

a femoral intramedullary rod;

a femoral alignment guide extending at an angle to the femoral intramedullary rod;

a femoral cut guide mountable to the femoral alignment guide;

a tibial extramedullary alignment guide; and

a tibial cut guide;

providing a surgeon with information for a method for performing the knee implant procedure comprising:

resecting a distal end of a femur of a knee including at least:

inserting the femoral intramedullary rod into an intramedullary canal of the femur;

positioning the femoral alignment guide so that a surface on the femoral alignment guide contacts a distal femoral condyle;

operably connecting the femoral cut guide to the femoral alignment guide and positioning the femoral cut guide to extend toward and generally along at least one of a medial side or a lateral side of the knee; and

guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade by using the femoral cut guide to create at least one resected surface on the distal end of the femur by guiding the long axis of the saw blade from the at least one of the medial side or the lateral side of the knee;

resecting a proximal end of a tibia of the knee including at least:

positioning the tibial extramedullary alignment guide;

operably connecting the tibial cut guide to the tibial extramedullary alignment guide and positioning the tibial cut guide generally adjacent at least a portion of an anterior side of the tibia and at least one of the medial side or the lateral side of the knee; and

guiding a cutting tool having a saw blade with a cutting edge at a distal end of a long axis of the saw blade by using the tibial cut guide to create at least one resected surface on the proximal end of the tibia by guiding the long axis of the saw blade from at least one of the medial side or the lateral side of the knee; and

implanting the implants by:

positioning the femoral implant with at least one fixation surface of the femoral implant generally adjacent the at least one resected surface of the femur; and

positioning the tibial implant with at least one fixation surface of the tibial implant generally adjacent to the at least one resected surface of the tibia.

27. The method of claim **9** wherein positioning the cutting guide in a position proximate an end of one of a femur or a tibia includes fixing the cutting guide to the end of one of the femur or the tibia using a connection mechanism having a long axis that is oriented generally parallel to the resected surface and extends into one of the femur or the tibia from one of the medial aspect or the lateral aspect.

28. The method of claim **9** wherein positioning the cutting guide in a position proximate an end of one of a femur or a tibia further comprises:

using an alignment mechanism operably coupled to the cutting guide to align the at least one guide surface relative to one of the femur or the tibia in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment mechanism to position the cutting guide in a desired location and orientation.

29. The method of claim **28** wherein using the alignment mechanism is performed by moving the at least one guide surface though at least a portion of an infinitely adjustable range of motion for the at least one of the at least three degrees of freedom.

30. The method of claim **28** wherein using an alignment mechanism operably coupled to the cuffing guide to align the at least one guide surface further includes adjusting the desired location and orientation of the cutting guide in each of varus-valgus, flexion-extension, internal-external rotation, anterior-posterior, medial-lateral, and proximal-distal degrees of freedom without invading an intra-medullary canal.

31. The method of claim **9** wherein cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis comprises plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion of the one of the femur or the tibia adjacent to the position of the cutting guide and a medial portion or a lateral portion of the one of the femur or the tibia across from and opposite to the position of the cutting guide.

32. The method of claim **9** wherein positioning the cutting guide is performed such that any portion of the slot facing the end of the one of the femur or the tibia from an anterior side extends to less than about one-half of a width of the at least one resected surface.

33. The method of claim **32** wherein cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis comprises plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion of the one of the femur or the tibia adjacent to the position of the cutting guide and

a medial portion or a lateral portion of the one of the femur or the tibia across from and opposite to the position of the cutting guide.

34. The method of claim **9** wherein positioning the cutting guide comprises using a drill guide adapted to be manipulated in at least five of six degrees of freedom to create an aperture in the one of the femur or the tibia having a long axis substantially parallel to the resected surface, the long axis of the aperture dictating a location and orientation of the resected surface in one translational degree of freedom and one rotational degree of freedom when the cutting guide is connected in a predetermined location and orientation with respect to the long axis of the aperture.

35. The method of claim **13** wherein positioning the tibial cut guide locates the tibial cut guide generally medially and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a lateral side of the tibia.

36. The method of claim **13** wherein positioning the tibial cut guide locates the tibial cut guide generally laterally and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a medial side of the tibia.

37. The method of claim **13** wherein positioning the femoral cut guide locates the femoral cut guide generally medially and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a lateral side of the femur.

38. The method of claim **13** wherein positioning the femoral cut guide locates the femoral cut guide generally laterally and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a medial side of the femur.

39. The method of claim **16** wherein the femoral cut guide extends mediolaterally for a width less than one-half of a width of the femur and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a contralateral compartment relative to the one of the medial side or the lateral side of the femur.

40. The method of claim **19** wherein the tibial cut guide extends mediolaterally for a width less than one-half of a width of the tibia and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a contralateral compartment relative to the one of the medial side or the lateral side of the tibia.

41. The method of claim **24** wherein positioning the cutting guide in a position proximate an end of one of a femur or a tibia includes fixing the cutting guide to the end of one of the femur or the tibia using a connection mechanism having a long axis that is oriented generally parallel to the resected surface and extends into one of the femur or the tibia from one of the medial aspect or the lateral aspect.

42. The method of claim **24** wherein positioning the cutting guide in a position proximate an end of one of a femur or a tibia further comprises:

using an alignment mechanism operably coupled to the cutting guide to align the at least one guide surface relative to one of the femur or the tibia in at least three degrees of freedom, at least one of the degrees of freedom being rotational; and

locking the alignment mechanism to position the cutting guide in a desired location and orientation.

43. The method of claim **42** wherein using the alignment mechanism is performed by moving the at least one guide surface through at least a portion of an infinitely adjustable range of motion for the at least one of the at least three degrees of freedom.

44. The method of claim **42** wherein using an alignment mechanism operably coupled to the cutting guide to align the at least one guide surface further includes adjusting the desired location and orientation of the cutting guide in each of varus-valgus, flexion-extension, internal-external rotation, anterior-posterior, medial-lateral, and proximal-distal degrees of freedom without invading an intra-medullary canal.

45. The method of claim **24** wherein cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis comprises plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion of the one of the femur or the tibia adjacent to the position of the cutting guide and a medial portion or a lateral portion of the one of the femur or the tibia across from and opposite to the position of the cutting guide.

46. The method of claim **24** wherein positioning the cutting guide is performed such any portion of the slot facing the end of the one of the femur or the tibia from an anterior side extends to less than about one-half of a width of the at least one resected surface.

47. The method of claim **46** wherein cutting the end of the one of the femur or the tibia by moving the cutting tool in a direction along the long axis comprises plunging the saw blade through the slot to create the resected surface on both a medial portion or a lateral portion of the one of the femur or the tibia adjacent to the position of the cutting guide and a medial portion or a lateral portion of the one of the femur or the tibia across from and opposite to the position of the cutting guide.

48. The method of claim **24** wherein positioning the cutting guide comprises using a drill guide adapted to be manipulated in at least five of six degrees of freedom to create an aperture in the one of the femur or the tibia having a long axis substantially parallel to the resected surface, the long axis of the aperture dictating a location and orientation of the resected surface in one translational degree of freedom and one rotational degree of freedom when the cutting guide is connected in a predetermined location and orientation with respect to the long axis of the aperture.

49. The method of claim **26** wherein positioning the tibial cut guide locates the tibial cut guide generally medially and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a lateral side of the tibia.

50. The method of claim **26** wherein positioning the tibial cut guide locates the tibial cut guide generally laterally and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a medial side of the tibia.

51. The method of claim **26** wherein positioning the femoral cut guide locates the femoral cut guide generally medially and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a lateral side of the femur.

52. The method of claim **26** wherein positioning the femoral cut guide locates the femoral cut guide generally laterally and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a medial side of the femur.

53. The method of claim **26** wherein the step of positioning the femoral cut guide positions the femoral cut guide to extend toward and generally along one of the medial side or the lateral side of the knee and wherein the femoral cut guide extends mediolaterally for a width less than one-half of a width of the femur and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the femoral cut guide further includes cutting a contralateral compartment relative to the one of the medial side or the lateral side of the femur.

54. The method of claim **26** wherein the step of positioning the tibial cut guide positions the tibial cut guide to extend toward and generally along one of the medial side or the lateral side of the knee and wherein the tibial cut guide extends mediolaterally for a width less than one-half of a width of the tibia and guiding the cutting tool having the saw blade with the cutting edge at the distal end of the long axis of the saw blade by using the tibial cut guide further includes cutting a contralateral compartment relative to the one of the medial side or the lateral side of the tibia.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

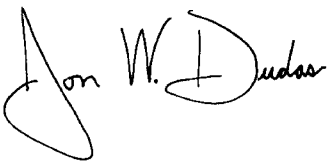
PATENT NO. : 7,344,541 B2
APPLICATION NO. : 10/756817
DATED : March 18, 2008
INVENTOR(S) : Timothy G. Haines

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 42, Claim 30, Line 39 “cuffing guide” should be --cutting guide--

Signed and Sealed this

First Day of July, 2008



JON W. DUDAS
Director of the United States Patent and Trademark Office

CERTIFICATE OF SERVICE

I certify that I served a copy of the foregoing Brief of Appellant on counsel of record on May 18, 2015, by e-mail at the following address:

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CERTIFICATE OF COMPLIANCE

Appellants Biomet Orthopedics, LLC and Biomet Manufacturing Corporation certify the following:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). Specifically, this brief contains 13,588 words, excluding parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii); and

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). Specifically, this brief has been prepared in a proportionally spaced typeface using MS Word 2007 in a 14 point Times New Roman font.

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